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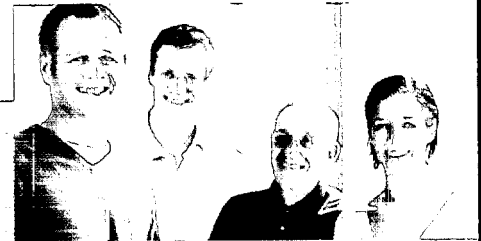
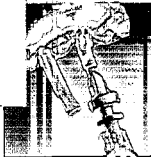
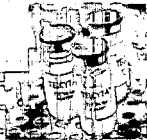
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# Innovating

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# Drug Development

## TELCYTA™

Indication	Clinical Trials	Phase 1	Phase 2	Phase 3
Ovarian Cancer	ASSIST-1 (Single Agent)			
	ASSIST-3 (Carboplatin Combination)			
	Carboplatin Combination			
	Doxil® Combination			
	Single Agent			
Non-Small Cell Lung Cancer	ASSIST-2 (Single Agent)			
	Cisplatin Combination (1st Line)			
	Carboplatin + Paclitaxel Combination (1st Line)			
	Docetaxel Combination			
	Single Agent			
Colorectal Cancer	Single Agent			
Breast Cancer	Single Agent			

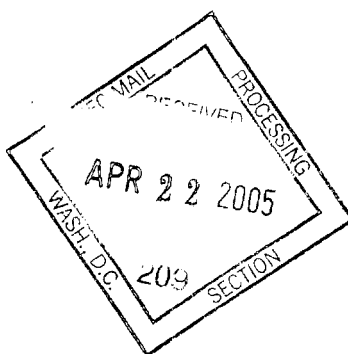
## TELINTRA™

Indication	Phase 1	Phase 2	Phase 3
Myelodysplastic Syndrome			
Oral Formulation (Pre-IND)			

## Small Molecule Programs from TRAP™ Technology

Target	Compounds Identified	Preclinical
Cancer	GST Inhibitor	
	Raf Kinase Inhibitor	
	Aurora Kinase Inhibitor	
	DNA Methyltransferase Inhibitor	
	PARG Inhibitor	
	IGF-1 Receptor Inhibitor	
	AKT Kinase Inhibitor	
Inflammatory Disease	MCP-1 Antagonist	

# To Our Stockholders



The ultimate goal of cancer treatment is to improve survival. Patients would of course prefer to have this improvement be the result of their cancer disappearing completely, a complete response, leading to a corresponding improvement in disease symptoms and overall quality of life. Only a few cancer drugs, such as the platinum based drugs, are presently capable of inducing complete responses in the solid tumors that we are studying: non-small cell lung, ovarian, breast and colorectal cancer. These complete responses occur infrequently and are accompanied by substantial toxicity.

Complete responses are difficult to achieve because solid tumors typically cannot be diagnosed until the tumor has already grown to at least 1 cm in diameter, corresponding to about 1 billion cancer cells. Before patients are even aware of the tumor, the uncontrolled cancer cell doubling which led to formation of the tumor has already occurred many times. A partial response is defined as shrinkage of at least 50% of the tumor and is a clear sign of cancer drug activity but millions of cancer cells remain. A complete response, however, requires destruction of at least 99.9% of the cancer cells, a much higher hurdle.

The discovery of new cancer drugs that can induce complete responses with acceptable toxicity requires significant innovation. TELCYTA™ is the product of an innovation in cancer drug development called “targeted activation” that is intended to retain the desirable profiles of both traditional and targeted therapies. As in targeted therapy, a metabolic difference between normal and cancer cells—increased GST P1-1 enzymatic activity—is exploited to activate TELCYTA preferentially within the cancer cell. This activation releases a very toxic molecule within the cancer cell that leads to its death.

TELCYTA has demonstrated a broad spectrum of activity including complete responses when administered alone and in combination in multiple cancer types throughout the clinical development program involving hundreds of patients. Both the anti-tumor activity of TELCYTA and the sparing of normal tissues may result from the relative targeting of activation to the cancer cell. Further, the highly reactive fragment released by TELCYTA interferes with multiple cancer cell processes, making it more difficult for the cancer cell to evade destruction. As a result, TELCYTA may provide an important complement to traditional and targeted cancer therapies.

2004 was as a very productive year for Telik as we reported important new clinical results, including data from the first studies of TELCYTA administered in combination with our most useful cancer drugs including platinum, taxanes, and anthracyclines. In these studies, TELCYTA contributed to tumor shrinkage and also appeared to augment the activity of the standard drugs without increasing toxicity. These improved outcomes could increase TELCYTA's ultimate potential to treat patients earlier in the course of their cancer. Based on these results, we initiated an additional registration trial, ASSIST-3, studying the combination of TELCYTA and carboplatin in second line ovarian cancer. In addition to ASSIST-3, registration trials are well underway testing TELCYTA as a single agent in advanced ovarian cancer (ASSIST-1) and non-small cell lung cancer (ASSIST-2). We await the results of these trials to confirm the magnitude of TELCYTA's safety and efficacy.

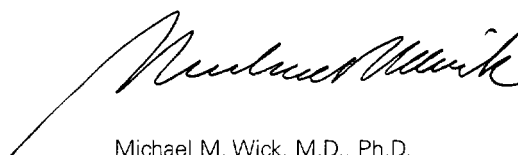
In 2004, we initiated the first trials in front-line non-small cell lung cancer as we continue to advance TELCYTA to earlier and larger patient populations. The more advanced of these trials is evaluating TELCYTA in combination with cisplatin. Also ongoing is a Phase 2 trial in which TELCYTA is added to a standard front-line non-small cell lung cancer regimen of carboplatin and paclitaxel. We will report the results later this year.

Our second product candidate, TELINTRA™, has shown promising Phase 2 activity in a pre leukemic condition called myelodysplastic syndrome (MDS) that afflicts an increasing number of patients, many of whom are elderly and require chronic treatment. Since TELINTRA functions by an innovative new mechanism as compared to drugs that are currently under study or available, it may complement and potentially be combined with these drugs and offer patients and physicians additional tools to treat MDS. We are planning to file an Investigational New Drug application this year to evaluate a more convenient oral dosage form to broaden the potential applications of TELINTRA.

Innovation is a continuing challenge as we build our product pipeline. We have set a goal of introducing additional innovative cancer product candidates that are discovered, internally or in collaboration with major academic cancer centers, using our TRAP™ computational drug discovery technology. We continue to invest in developing the technology and expanding our group of scientific collaborators.

Although continuing innovation will lead to improved health and welfare for cancer patients, we must remain focused on completing the necessary tasks that will bring Telik's treatments to the clinic. I am pleased to be a member of the Telik team that is working to achieve these goals.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael M. Wick". The signature is fluid and cursive, with a long, sweeping underline that extends to the left.

Michael M. Wick, M.D., Ph.D.

*Chairman and Chief Executive Officer*

# Form 10-K

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended December 31, 2004

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number: 0-31265

**TELIK, INC.**

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

93-0987903

(I.R.S. Employer  
Identification No.)

3165 Porter Drive, Palo Alto, CA 94304

(Address, including zip code, of principal executive offices)

Registrant's telephone number, including area code: (650) 845-7700

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, \$0.01 par value per share

(Title of Class)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period than the Registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether Registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). YES ☒ NO ☐

The aggregate market value of the voting stock held by non-affiliates of the Registrant was approximately \$1,037,182,817 as of June 30, 2004, based upon the closing sale price on the Nasdaq National Market reported for such date. The determination of affiliate status for the purposes of this calculation is not necessarily a conclusive determination for other purposes. The calculation excludes approximately 241,110 shares held by directors, officers and stockholders whose ownership exceeded five percent of the Registrant's outstanding Common Stock as of June 30, 2004. Exclusion of these shares should not be construed to indicate that such person controls, is controlled by or is under common control with the Registrant.

There were 51,946,638 shares of Registrant's Common Stock issued and outstanding as of February 28, 2005.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III incorporate information by reference from the definitive proxy statement for the Registrant's Annual Meeting of Stockholders to be filed by April 30, 2005.

**TELIK, INC.**  
**2004 ANNUAL REPORT ON FORM 10-K**  
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## Disclosure Regarding Forward-Looking Statements

This annual report on Form 10-K, including the documents that we incorporate by reference, contains statements indicating expectations about future performance and other forward-looking statements that involve risks and uncertainties. We usually use words such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “future,” “intend,” “potential,” or “continue” or the negative of these terms or similar expressions to identify forward-looking statements. These statements appear throughout the Form 10-K and are statements regarding our current intent, belief, or expectation, primarily with respect to our operations and related industry developments. Examples of these statements include, but are not limited to, statements regarding the following: the implications of positive interim or final results of our Phase 2 clinical and Phase 3 registration trials, the progress and timing of our research programs, including clinical testing, our anticipated timing for filing additional IND, or Investigational New Drug, applications with the Food and Drug Administration for the initiation or completion of Phase 1, Phase 2 or Phase 3 testing for any of our product candidates, the extent to which our issued and pending patents may protect our products and technology, our ability to identify new product candidates using TRAP technology (our proprietary Target-Related Affinity Profiling technology, which is discussed below), the potential of such product candidates to lead to the development of safer or more effective therapies, our ability to develop the technology derived from our collaborations and to enter into additional TRAP collaborations, our future operating expenses, our future losses, our future expenditures for research and development, the sufficiency of our cash resources and our use of proceeds from our follow-on public offering in February 2005. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this annual report. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks faced by us and described in the section of Item 7 entitled “Risk Factors,” and elsewhere in this annual report. Any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events.

“TELIK,” the Telik logo, TRAP, TELCYTA and TELINTRA are trademarks of Telik, Inc. All other brand names or trademarks appearing in this annual report are the property of their respective holders.



## PART I

### Item 1. Business.

#### Overview

Telik, Inc. was incorporated in Delaware in 1988 and is a biopharmaceutical company working to discover, develop and commercialize innovative small molecule drugs to treat diseases. Our most advanced drug development candidate is TELCYTA (TLK286), a tumor-activated small molecule. We have three on-going Phase 3 registration clinical trials for TELCYTA. The first Phase 3 clinical trial (ASSIST-1) is for the treatment of advanced ovarian cancer. The second Phase 3 clinical trial (ASSIST-2) is for the treatment of advanced non-small cell lung cancer. The third Phase 3 clinical trial (ASSIST-3) evaluates TELCYTA in combination with carboplatin for the treatment of platinum resistant or refractory ovarian cancer. We are also conducting two Phase 2 clinical trials of TELCYTA for the treatment of Stage IIIb or IV non-small cell lung cancer for patients who have not previously received chemotherapy. One clinical trial is in combination with cisplatin, and the other clinical trial is in combination with carboplatin and paclitaxel. To date, we have not obtained regulatory approval for the commercial sale of any products, and we have not received any revenue from the commercial sale of products.

TELINTRA (TLK199), our second product candidate, is in a Phase 2 clinical trial in myelodysplastic syndrome, or MDS, a form of pre-leukemia. We discovered our product candidates using our proprietary drug discovery technology, TRAP, which we believe enables the rapid and efficient discovery of small molecule product candidates.

TELCYTA, our lead product candidate, is a small molecule tumor-activated cancer product candidate that binds to glutathione S-transferase P1-1, or GST P1-1, a protein that is elevated in many human cancers, such as ovarian, non-small cell lung, colorectal, breast and other types of cancer. GST P1-1 levels are often further elevated following treatment with many standard chemotherapy drugs, and this elevation is associated with the development of resistance to these drugs. When TELCYTA binds to GST P1-1 inside a cancer cell, a chemical reaction occurs, releasing fragments of TELCYTA that cause programmed cancer cell death, or apoptosis.

TELCYTA has shown clinical antitumor activity alone and in combination in multiple Phase 2 clinical trials in refractory or resistant ovarian, non-small cell lung, breast and colorectal cancer. Positive results from three combination trials were presented at the annual meeting of the American Society of Clinical Oncology in June 2004 and at the Tenth Biannual International Gynecologic Cancer Society meeting in October 2004.

We have completed patient enrollment in ASSIST-1 and continue to enroll patients in ASSIST-2. We have received a Special Protocol Assessment review by the U.S. Food and Drug Administration ("FDA") and a Fast Track designation for ASSIST-1 and ASSIST-2. We initiated ASSIST-3, a Phase 3 registration trial of TELCYTA in combination with carboplatin as second-line therapy in platinum refractory or resistant ovarian cancer, in December 2004. We have retained worldwide commercialization rights for TELCYTA.

TELINTRA, our second cancer product candidate, is a small molecule bone marrow stimulant that we are developing for the treatment of blood disorders associated with low blood cell levels, such as neutropenia, anemia or thrombocytopenia. These conditions are associated with MDS. Neutropenia and anemia are also toxic side effects of cancer chemotherapy. TELINTRA activates signaling pathways that lead to the growth and differentiation of blood cells. In preclinical tests, TELINTRA has been shown to stimulate white blood cell production. This effect may provide the basis for the treatment of MDS and other conditions associated with low blood cell production with TELINTRA. Interim results were presented at the American Society of Hematology in 2004 and showed positive effects in patients with MDS. We have retained worldwide commercialization rights for TELINTRA.

Our next product candidate may be selected from our on-going discovery research programs and our collaborations with leading cancer centers. These include compounds intended to be inhibitors of GST, AURORA kinase and other enzymes that we believe are critical to the growth of cancer cells and intended for the treatment of cancer, as well as MCP-1 inhibitors that have potential for the treatment of cancer and inflammatory diseases.

We discovered all of our product candidates using our proprietary technology, Target-Related Affinity Profiling, or TRAP, which we believe enables the rapid and efficient discovery of small molecule product candidates. TRAP exploits a fundamental property of all drugs, which is their selective interaction with proteins. By developing a profile of how small molecule chemicals interact with a reference panel of proteins, we believe we can identify compounds that are active against disease-related protein targets faster than with alternative technologies.

## **Our Strategy**

Our goal is to become a biopharmaceutical company focused on discovering, developing and commercializing innovative small molecule drugs to treat cancer and inflammatory diseases. Key elements of our strategy are to:

- **Develop small molecule drugs for major disease areas.** We intend to develop small molecule drugs to address unmet needs in the areas of cancer and inflammatory diseases. The number of patients with these diseases has been increasing due primarily to the aging population. This has led to a growing demand for new drugs that offer competitive advantages over existing products, such as improved effectiveness and reduced side effects. The advantages of small molecule drugs over therapeutic proteins include the ease of manufacturing and administration, the potential for oral dosing and applicability to a wider range of disease targets, including those inside the cell.
- **Retain commercial rights to our product candidates.** We plan to seek to retain significant commercial rights to our product candidates by conducting clinical development activities at least through initial proof of efficacy in humans. Because the development process for cancer drugs is relatively short and well defined, the cost and time required to bring new drugs to market is typically significantly less than that required for other therapeutic categories. For diseases that require larger and longer clinical trials, we plan to share the risks and costs of development by partnering these programs before completion of registration trials, which we expect may require granting commercialization rights to our collaborators. Our goal is to develop and commercialize our cancer product candidates in North America. We believe that the hospital-based cancer market in the United States is readily accessible by a limited sales and marketing presence due to the concentrated market of prescribing physicians coupled with the substantial unmet therapeutic needs. As appropriate, we will seek to establish collaborations with multinational pharmaceutical companies to assist in the commercialization of our product candidates.
- **Select targets strategically.** We believe that we can apply our TRAP drug discovery technology to virtually any protein target. We regularly review the progress of scientific and clinical research in important disease areas to identify targets with commercial potential. By careful selection of targets, we intend to develop product candidates with a clear path to regulatory approval and the potential to show early evidence of clinical efficacy. This strategy should allow us to reduce the risk inherent in drug discovery and accelerate the commercialization of our product candidates.
- **Use TRAP to sustain a pipeline of product candidates.** We believe our proprietary TRAP drug discovery platform allows us to rapidly and efficiently identify small molecules active against potential disease targets. We have used and plan to continue to use this platform to provide a pipeline of future product development candidates generated internally or through collaborations. For example, through a collaboration with the University of Arizona Cancer Center, we are applying TRAP to identify novel compounds active against a wide range of potential cancer targets. We plan to secure additional academic partners for the use of TRAP technology. We also have entered into corporate collaborations, such as with Hoffman-La Roche Inc., to assist our partners in identifying product candidates for promising therapeutic targets.

## Product Candidate Pipeline

We have concentrated our efforts in cancer and inflammatory diseases. We periodically reevaluate and prioritize our research programs. The following table summarizes key information about our current product candidate pipeline:

Product candidate	Clinical indication	Development status	Commercialization rights
<b>Clinical</b>			
<b>TELCYTA</b> Tumor-activated cancer product candidate	Ovarian cancer Non-small cell lung cancer Ovarian cancer, 2 <sup>nd</sup> line (carboplatin combination vs. Doxil) Non-small cell lung cancer (1 <sup>st</sup> line, with cisplatin) Non-small cell lung cancer (1 <sup>st</sup> line, with carboplatin and paclitaxel) Ovarian cancer Non-small cell lung cancer Colorectal cancer Breast cancer Ovarian cancer (Doxil combination) Ovarian cancer (carboplatin combination) Non-small cell lung cancer (Taxotere combination)	Phase 3 (ASSIST-1)—on-going Phase 3 (ASSIST-2)—on-going Phase 3 (ASSIST-3)—on-going  Phase 2—on-going  Phase 2—on-going  Phase 2—completed Phase 2—completed Phase 2—completed Phase 2—completed Phase 2—completed  Phase 2—completed  Phase 2—completed	Worldwide
<b>TELINTRA</b> Bone marrow stimulant	MDS	Phase 2—on-going	Worldwide
<b>Preclinical</b>			
<b>GST inhibitor</b>	Cancer	Small molecule inhibitors discovered	Worldwide
<b>Raf kinase inhibitor</b>	Cancer	Small molecule inhibitors discovered	Worldwide
<b>AURORA kinase inhibitor</b>	Cancer	Small molecule inhibitors discovered	Worldwide
<b>DNA methyl transferase inhibitor</b>	Cancer	Small molecule inhibitors discovered	Worldwide
<b>Poly(ADP-ribose) Glycohydrolase</b>	Cancer	Small molecule inhibitors discovered	Worldwide
<b>IGF-1 inhibitor</b>	Cancer	Small molecule inhibitors discovered	Worldwide
<b>AKT kinase inhibitor</b>	Cancer	Small molecule inhibitors discovered	Worldwide
<b>MCP-1 antagonist</b>	Rheumatoid arthritis, asthma, atherosclerosis, multiple sclerosis, inflammatory bowel disease, cancer	Preclinical and safety assessment on-going	North and South America and jointly in Europe

## Product Development Programs

### *Cancer*

Our two most advanced product candidates, TELCYTA and TELINTRA, are being developed to treat cancers for which there is significant demand for new therapies. Cancer is the second leading cause of death in the United States according to the American Cancer Society's 2004 Cancer Facts and Figures. The five-year survival rates for patients with cancers that have spread from their original site are poor. These poor survival rates reflect the limitations of current treatments and the development of resistance to available treatments. In addition, current treatments are often associated with severe toxic side effects.

#### *TELCYTA—Tumor-activated cancer product candidate*

TELCYTA is a small molecule product candidate we are developing for the treatment of cancer. TELCYTA binds to glutathione S-transferase, or GST, a protein known to play an important role in the development of resistance to commonly used chemotherapeutic drugs. GST P1-1 is a type of GST that is elevated in many cancers and is often further elevated following treatment with standard chemotherapeutic drugs. When TELCYTA binds to GST P1-1, it releases a fragment with a proven mechanism of killing cancer cells as well as other reactive agents. In contrast to the usual situation in which GST is involved in the destruction of chemotherapeutic drugs, GST activates TELCYTA when TELCYTA reaches its cellular target. In this way, TELCYTA kills cancer cells by inducing cell death through a process called apoptosis.

TELCYTA has been evaluated in multiple clinical trials. Results from these clinical trials indicate that TELCYTA is generally well-tolerated, with mostly mild to moderate side effects, particularly when compared to the side effects and toxicities of standard chemotherapeutic drugs. This tolerability profile may be an important clinical advantage for TELCYTA. Since combination drug regimens are commonly used in cancer treatment, the tolerability profile of TELCYTA and its lack of overlapping toxicities with standard chemotherapeutic drugs suggest TELCYTA may be well suited for inclusion in combination chemotherapy regimens.

We have three on-going Phase 3 registration trials with TELCYTA. The first Phase 3 clinical trial (ASSIST-1) is for the treatment of advanced ovarian cancer. The second Phase 3 clinical trial (ASSIST-2) is for the treatment of advanced non-small cell lung cancer. The third Phase 3 clinical trial (ASSIST-3) evaluates TELCYTA in combination with carboplatin versus Doxil as second-line therapy in platinum resistant or refractory ovarian cancer.

In June 2004, at the American Society of Clinical Oncology annual meeting, we announced positive results from three Phase 2 clinical trials testing TELCYTA in combination with standard chemotherapeutic drugs, including TELCYTA in combination with docetaxel in platinum resistant non-small cell lung cancer, TELCYTA in combination with carboplatin and TELCYTA in combination with Doxil in platinum refractory or resistant ovarian cancer. The data from these clinical trials demonstrate that the combination of TELCYTA with standard chemotherapeutic drugs may provide significant clinical benefit with durable responses without new or unanticipated toxicities and has the potential to re-sensitize platinum refractory or resistant ovarian cancer to platinum. In October 2004, we announced additional positive data from the Phase 2 clinical trials of TELCYTA administered in combination with carboplatin and Doxil in platinum refractory or resistant ovarian cancer at the Tenth Biannual International Gynecologic Cancer Society meeting.

In 2004, we initiated two Phase 2 clinical trials of TELCYTA for the treatment of Stage IIIB or IV non-small cell lung cancer for patients who have not previously received chemotherapy. One clinical trial is in combination with cisplatin, and the other clinical trial is in combination with carboplatin and paclitaxel. Platinum and taxane-based drug combinations are the current standard for the front-line chemotherapy of lung and ovarian cancer.

#### *TELINTRA—Bone marrow stimulant*

TELINTRA is a small molecule product candidate that we believe has the potential to increase white blood cell counts in cancer patients. In addition to killing cancer cells, chemotherapeutic drugs also kill rapidly dividing normal cells. These include normal cells found in bone marrow that eventually become white blood cells, red blood cells and platelets. For example, lowered levels of a type of white blood cells, called neutrophils, cause a condition called neutropenia. Neutropenia is a common side effect of chemotherapy and renders the already weakened cancer patient susceptible to life-threatening infections. Low blood cell levels are also found in a number of pre-leukemic conditions, such as MDS, that may require treatment to prevent infections.

Granulocyte colony stimulating factor, or G-CSF, is the current standard therapy for the treatment of neutropenia, since it accelerates the recovery of white blood cells to a normal level. G-CSF acts by binding to a receptor protein on the surface of the cell and activating a signaling pathway within the cell. This signal causes white blood cells in the bone marrow to divide and mature, increasing the number of white cells in the blood capable of fighting infection. Evidence from our preclinical studies suggests that TELINTRA acts upon the same signaling pathway that is activated by G-CSF.

Our Phase 2 clinical trial in patients with MDS, a pre-leukemic condition, is on-going and has not identified a dose limiting toxicity. MDS is a disease characterized by defects in the blood-producing cells of the bone marrow, in which low blood cell levels occur. We presented positive interim data at the American Society of Hematology annual meeting in December 2004. In this study, clinically significant improvement was observed across all major MDS FAB subtypes and in all blood cell lineages. TELINTRA was well-tolerated in this predominantly elderly patient population, and enrollment is on-going.

TELINTRA is expected to offer the advantages of a small molecule drug over a therapeutic protein, including ease of manufacturing and the potential for oral administration. The potential oral administration of TELINTRA may allow us to offer a product that is an attractive alternative to the current market for drugs that stimulate the production of white or red blood cells. We have retained worldwide commercial rights to TELINTRA.

#### **Research Discovery Programs**

In addition to generating our current clinical product portfolio, TRAP has allowed us to build our research pipeline with product candidates against targets in cancer and inflammatory diseases. We have chosen to pursue those protein targets that have engendered a high level of interest in the drug discovery community, address important unmet clinical needs and whose modulation are expected to have a beneficial effect in treating a given disease. We are continually evaluating and prioritizing our early stage programs. We retain worldwide commercialization rights for all of our preclinical candidates except MCP-1, for which we retain rights in North and South America while sharing rights in Europe.

##### *GST inhibitor*

As part of our on-going program in GST from which we have identified both of our lead compounds, TELCYTA and TELINTRA, we have prepared and tested compounds that have new toxic fragments attached to the GST recognition site. Several of these compounds have shown the ability to kill human cancer cells in the laboratory. We believe that these novel compounds leverage our GST P1-1 technology platform.

##### *Raf kinase inhibitor*

Mutations of the Ras protein are found in many types of tumors and can lead to abnormal activation of the Raf kinase pathway, resulting in an increase in cancer cell proliferation. Inhibition of Raf kinase activity can lead to the inhibition of tumor growth. We have identified small molecule inhibitors of the Raf kinase pathway.

#### *AURORA kinase inhibitor*

Aurora kinases are enzymes expressed in human cells that are found to be elevated in many solid tumors, in particular pancreatic cancer. Inhibition of aurora kinase activity can lead to the inhibition of tumor growth. In collaboration with the Arizona Cancer Center, we have identified small molecule inhibitors of aurora kinase activity.

#### *DNA methyltransferase inhibitor*

DNA methyltransferase is required to maintain genetic stability within cells. Changes in DNA methyltransferase activity can lead to malignancy by causing modifications to DNA. Inhibition of DNA methyltransferase has been shown to inhibit tumor growth in mouse models of cancer. In collaboration with the Arizona Cancer Center, we have identified small molecule inhibitors of DNA methyltransferase.

#### *PARG (Poly(ADP-ribose) Glycohydrolase) inhibitor*

DNA damage in cells can lead to cancer. DNA is repaired by a process that often involves the transient modification of proteins by the enzyme PARG. Inhibitors of PARG, such as those we have identified in collaboration with the Arizona Cancer Center, may block DNA repair and lead to death of cancer cells.

#### *IGF-1 receptor inhibitor*

Using our TRAP technology, we have identified small molecules that selectively inhibit protein targets that are thought to be important to the growth and spread of cancer. Insulin-like growth factor-1, or IGF-1, is an important target for cancer therapy. Blood levels of IGF-1 are increased in prostate cancer patients, and increases in the amount of the IGF-1 receptor predict a poor prognosis in breast cancer. We have identified two families of small molecules that inhibit the interaction of IGF-1 with its receptor as well as the growth of cancer cells.

#### *AKT kinase*

As part of our TRAP collaboration with Vanderbilt-Ingram Cancer Center, we have identified a series of small molecule inhibitors of AKT kinase, an enzyme believed to be important in the growth of cancer cells.

#### *MCP-1 antagonists for cancer and inflammatory diseases*

Inflammation is an important response of the body to injury and infection. If inflammation becomes excessive or prolonged, it can lead to pathological conditions, including asthma, inflammatory bowel disease, multiple sclerosis, psoriasis, rheumatoid arthritis and septic shock. An early step in the inflammatory response is the attraction of white blood cells, or leukocytes, from the circulatory system to damaged or infected tissue by messenger molecules called chemokines.

Our research has identified inhibitors selected for an important chemokine mediator of the inflammatory response: MCP-1. These inhibitors block the interaction of MCP-1 with its protein receptor and are active in animal models of inflammatory disease.

We have exclusive commercialization rights in North America and South America. We share commercialization rights with our collaborator, Sanwa, in Europe.

#### **TRAP Technology**

Our Target-Related Affinity Profiling, or TRAP, drug discovery technology is designed to rapidly and efficiently identify small molecule product candidates that act on disease related protein targets. TRAP technology offers solutions to the two major challenges facing drug discovery: the explosive growth in the

number of new protein targets generated by the advances in genomics and the intrinsic limitations of the Ultra High Throughput Screening, or UHTS, approach. TRAP offers several competitive advantages over UHTS, because it is able to accommodate thousands, rather than hundreds, of targets, is cost-effective to screen unproven targets for the purpose of validation and avoids the use of highly simplified assays.

We have discovered that there are a limited number of ways that proteins interact with small molecules and that these interactions can be simulated using a carefully selected panel of diverse proteins. TRAP takes advantage of this discovery to profile the interactions of small molecules with proteins using a panel of less than 20 proteins selected for their distinct patterns of interacting with small molecules. We believe that our panel of proteins simulates, either individually or in combination, most of the significant interactions between a small molecule and a protein. Furthermore, TRAP measures the diversity of compounds in a way that cannot be explained on the basis of chemical structure alone. Compounds that are structurally similar can have very different affinities for proteins and other biological properties, and, conversely, compounds that are structurally diverse may have similar affinities for proteins and other biological properties.

By comparing the relative strengths of the interaction of a small molecule with each panel protein, a protein affinity profile, or fingerprint, is produced for the small molecule. One type of assay we use, called a binding assay, measures the interaction of a panel protein with a specially designed binding partner, or ligand, in the presence of a small molecule. If the small molecule has an affinity for the same site on the panel protein as the ligand, the amount of ligand that binds will be reduced. This decrease in the amount of the ligand that binds to each panel protein comprises the small molecule's fingerprint.

Using these fingerprints, we select a small subset of compounds, which we call the training set, that is sufficiently diverse in its protein recognition characteristics to represent our entire collection, or library, of small molecules. We screen this training set against the target of interest and use the resulting data to predict the type of small molecule-protein interactions present in the target. A model of small molecule interactions with the target is generated by mathematically combining the individual interactions of TRAP panel proteins, where the panel proteins to be included in the model are determined by the affinities of the initial subset of compounds for the target. We can then select from the library those compounds that prefer these types of interactions for assay. We have developed a set of computational tools, in the form of chemoinformatics algorithms, which are used to scan the library for patterns of protein affinity, since these patterns appear to correlate best with biological activity. The majority of active compounds in our library that are pharmaceutically active against a given target can be identified after screening as few as 200 compounds.

We have used TRAP to assemble our library of small molecules, which is enriched by compounds that interact with proteins in a selective fashion and contains multiple compounds that can undergo each mode of protein interaction. We believe that this process creates a small molecule library with a greater likelihood of containing a compound that interacts with any specified protein, thus having a higher probability of generating product candidates than a conventionally or randomly assembled library. As a consequence, TRAP identifies those small molecules with a higher probability of being product candidates from within the universe of possible compounds, allowing their assembly into a manageable product discovery library. All of the known products that we have examined lie within the bounds of the library defined by TRAP.

The ability of TRAP to identify active compounds after screening only a few hundred samples overcomes many of the limitations of UHTS. TRAP does not require assays capable of screening millions of compounds, thereby decreasing the time and resources necessary for assay development. TRAP permits the selection of a given target of interest from a much wider universe of targets by reducing the need to acquire targets and assay technologies and allows more physiologically relevant assay systems to be used. In addition, TRAP eliminates the need for large compound collections and sophisticated and expensive automation to support them, further lowering the financial barrier to screening and permitting its application to emerging biopharmaceutical companies. Finally, the overall efficiency and economy of TRAP allow multiple targets to be pursued simultaneously and permit the screening of higher risk, but potentially more valuable, targets.

We will continue to increase our collection of small molecules, as well as to refine the panel of proteins used to create fingerprints. In addition, we will explore the expansion of our chemoinformatics algorithms and the application of the technology to delineate other properties of small molecules, such as their behavior in the body, their toxicological profiles and absorption, distribution, metabolism and excretion characteristics.

### **Collaborative Relationships**

We expect to enter into collaborative arrangements with third parties for clinical trials, development, manufacturing, regulatory approvals or commercialization of some of our product candidates, particularly outside North America, or in disease areas requiring larger and longer clinical trials.

We have established a number of joint discovery programs with other pharmaceutical, biotechnology and genomics companies. These collaborations exploit our TRAP technology platform and have the potential to identify new product development and commercialization opportunities either independently or pursuant to expanded collaborations. In addition, these collaborations have provided funding for our internal research and development programs.

These collaborations include the following:

#### *Sanwa*

In 1996, we entered into a screening services agreement with a Japanese pharmaceutical company, Sanwa Kagaku Kenkyusho Co., Ltd. to employ our proprietary TRAP technology to identify compounds that are active against biological targets. In September 1997 and October 1998, this agreement was amended to increase the number of targets, extend the term of the agreement and include the optimization of lead compounds for a period of two years. The agreement was further amended in March 2002 to clarify certain procedures for optimization of lead compounds, establish dates by which we would file at least one patent in three different categories of compounds, and permit Sanwa to submit to the screening program targets obtained from third parties. We concluded the optimization of a lead compound identified through the use of our TRAP technology in May 2003. Under the agreement, Sanwa has exclusive rights in Japan, Korea, Taiwan and China to commercialize the active compounds and inventions relating to compounds discovered in the collaborations. We have equivalent exclusive rights in North and South America. Elsewhere in the world, we will share with Sanwa all revenues arising from the active compounds and related inventions. The agreement will terminate on December 20, 2006. Either party may terminate the agreement at any time with notice upon material breach of obligations by the other party.

#### *The University of Arizona*

In January 2001, we entered into a research and license agreement with the Arizona Cancer Center at the University of Arizona to use our TRAP technology for the identification of small molecule compounds active against cancer related drug targets. The Arizona Cancer Center has successfully conducted biologic assays to screen TRAP-generated compounds for pharmacologic activity and we have selected four new compounds for further development. We have exclusive worldwide rights to develop and commercialize compounds that we selected and will use the Arizona Cancer Center as a preferred clinical site for our oncology drug development programs arising from this collaboration. In July 2002, we exercised our option to obtain exclusive worldwide rights to intellectual property, including small molecule product candidates, for four cancer targets. The license agreement will continue until the expiration of the patents covering such compounds.

#### *Vanderbilt-Ingram Cancer Center*

In December 2002, we entered into a research and license agreement with the Vanderbilt-Ingram Center at Vanderbilt University to use our TRAP technology for the identification of small molecule compounds active against cancer related targets. We will have the right to select compounds arising from the collaboration for further development. The research term of the agreement will terminate on March 15, 2005 and, if no compounds are selected for further development, the agreement will expire.



## Hoffmann-La Roche

In March 2003, we entered into a screening and license agreement with Hoffmann-La Roche, Inc. or Roche, to utilize our TRAP technology to identify product candidates active against a pharmaceutical target selected by Roche. We are entitled to receive certain payments upon acceptance of drug compounds by Roche.

### Patents and Proprietary Information

Patents and other proprietary rights are very important to our business. If we have enforceable patents of sufficient scope, it can be more difficult for our competitors to use our technology to create competitive products or to obtain patents that prevent us from using technology we create. As part of our business strategy, our policy is to actively file patent applications in the United States and internationally to cover new chemical compounds, pharmaceutical compositions, methods of preparation of the compounds and compositions and therapeutic uses of the compounds and compositions, methods related to our TRAP technology, and improvements in each of these. We also rely on trade secret information, technical know-how, innovation and agreements with third parties to continuously expand and protect our competitive position.

We have a number of patents and patent applications related to our compounds and other technology, but we cannot be certain that issued patents will be enforceable or provide adequate protection or that the pending patent applications will issue as patents. The following table shows the actual or estimated expiration dates in the United States and internationally for the primary patents and for patents that may issue from pending applications that cover our TRAP technology and the compounds in our product candidates.

	US patent expirations	Foreign patent expirations
TRAP .....	2014	2015*
Product candidates		
TELCYTA .....	2013	2014*
TELINTRA .....	2014	2014*

\* Includes pending applications

We may obtain patents for our compounds many years before we obtain marketing approval for them. We can generally apply for patent term extensions once the marketing approvals are obtained.

We also rely on trade secret information, technical know-how, innovation and agreements with third parties to continuously expand and protect our proprietary position. We require our employees and consultants to execute non-disclosure and assignment of invention agreements on commencement of their employment or engagement. We do not disclose our trade secrets (including significant aspects of our TRAP technology) outside Telik except where disclosure is essential to our business, and we require those individuals, companies and institutions doing business with us, including TRAP collaborators, to execute agreements to protect our trade secrets.

### Competition

Competition in the pharmaceutical and biotechnology industries is intense. The drugs that we are developing will have to compete with existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. Many pharmaceutical or biotechnology companies have products on the market and are actively engaged in the research and development of products that are competitive with our potential products. Many of these companies and institutions, either alone or together with their collaborative partners, have substantially greater financial, manufacturing, sales, distribution and technical resources and more experience in research and development,

clinical trials and regulatory matters, than we do. In addition, our competitors may succeed in developing technologies and drugs that are more effective, better tolerated or less costly than any which are being developed by us or which would render our technology or potential drugs obsolete or noncompetitive.

### **Regulatory Considerations**

The manufacturing and marketing of our potential products and our on-going research and development activities are subject to extensive regulation by numerous governmental authorities in the United States and other countries. In the United States, pharmaceutical products are subject to rigorous review by the FDA under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act and other federal statutes and regulations. Non-compliance with applicable requirements can result in fines, recall or seizure of products, total or partial suspension of production, refusal of the government to approve marketing applications or allow us to enter into supply contracts and criminal prosecution. The FDA also has the authority to revoke previously granted marketing authorizations.

Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each indication to establish a product candidate's safety and efficacy. The approval process may take many years, requires the expenditure of substantial resources, may involve post-marketing surveillance and may involve on-going requirements for post-marketing studies. The FDA may also require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. With respect to patented products or technologies, delays imposed by the governmental approval process may materially reduce the period during which we will have exclusive rights to exploit them.

Preclinical studies involve laboratory evaluation of product characteristics and animal studies to assess the initial efficacy and safety of the product. The FDA under its Good Laboratory Practices regulations regulates preclinical studies. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring these studies to be replicated. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must be approved by the FDA before we can commence clinical trials in humans. Unless the FDA objects to an IND, the IND will become effective 30 days following its receipt by the FDA.

Clinical trials involve the administration of the investigational product to humans under the supervision of a qualified principal investigator. Clinical trials must be conducted in accordance with Good Clinical Practice, or GCP, under protocols submitted to the FDA as part of the IND. In addition, each clinical trial must be approved and conducted under the auspices of an Investigational Review Board, or IRB, and with patient informed consent. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possibility of liability of the institution conducting the trial.

Clinical trials are conducted in three sequential phases but the phases may overlap. Phase 1 clinical trials may be performed in healthy human subjects or, depending on the disease, in patients. The goal of Phase 1 clinical trials is to establish initial data about the safety and tolerance of the product in humans. In Phase 2 clinical trials, in addition to safety, the efficacy of the product is evaluated in a limited number of patients with the target disease. Phase 3 clinical trials typically involve additional testing for safety and clinical efficacy in expanded, large-scale, multi-center studies of patients with the target disease. We have engaged contract research organizations, or CROs, to facilitate the administration of our Phase 3 registration trials.

We and all of our contract manufacturers are required to comply with the applicable FDA current Good Manufacturing Practice, or cGMP, regulations. Good Manufacturing Practice regulations include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to inspection by the FDA. These facilities must be approved before we can use them in the commercial manufacture of our products.

Outside the United States, our ability to market a product is contingent upon receiving marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Union registration procedures are available to companies wishing to market a product in more than one European Union member state. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization will be granted.

## **Manufacturing**

We are using third party manufacturers to produce clinical supplies of TELCYTA under cGMP regulations. We are conducting process development testing with drug manufacturers to scale up production of adequate clinical supplies of TELINTRA in a liposomal formulation.

We are currently dependent on a single source of supply of the active ingredient in TELCYTA, Organichem Corporation. In July 2004, we entered into an agreement with Organichem Corporation under which Organichem will manufacture and supply to us the active ingredient in TELCYTA for clinical and commercial purposes. We and Organichem have agreed on a pricing schedule for such supply, which will be subject to future renegotiation after the lapse of a defined time period. Organichem has agreed to maintain sufficient capacity to satisfy its supply obligations under the agreement, and we are entitled to reduced prices in the event of a significant production shortfall. For a number of years, we are obligated to purchase from Organichem a significant percentage of our United States requirements for the active ingredient in TELCYTA. Our agreement with Organichem will remain in force until it is terminated through one of the following mechanisms. Either party may terminate the agreement for an uncured or incurable breach of other party, or immediately upon a series of material breaches, and we have the right to terminate the agreement if TELCYTA is not approved for commercial sale by the FDA or if such approval is revoked. We also have the right to terminate the agreement upon repeated production shortfalls by Organichem. Neither party has the right to terminate the agreement at will until several years after the FDA approves TELCYTA for commercial sale.

We recently entered into an agreement with a second source for supply of the active ingredient. While we are working to qualify this additional supplier, there is no certainty that this will occur. We are currently dependent upon two sources for the drug product manufacture of TELCYTA.

We presently depend upon a single source of supply for clinical quantities of the active ingredient in TELINTRA, Bachem Corporation. We recently entered into an agreement with a second source for supply of the active ingredient, and are working to qualify this additional supplier. We also depend upon a single source of supply for a key excipient used in the manufacture of TELINTRA, Lipoid GmbH. While we are evaluating potential alternative sources of these materials, we have no such alternative sources that are immediately available. Cardinal Health, Inc. is currently our sole drug product manufacturer of TELINTRA. We have entered into an agreement with a second drug product manufacturer and are working to qualify this additional manufacturing source.

We intend to continue to use third-party contract manufacturers or corporate collaborators for the production of material for use in preclinical studies, clinical trials, manufacture of future products and commercialization. The manufacture of our potential products for preclinical studies and clinical trials and commercial purposes is subject to cGMP regulations promulgated by the FDA and to other applicable domestic and foreign regulations.

## **Research and Development**

We believe that our on-going research and development efforts are very important to our success. Our goal is to develop small molecule drugs for major disease areas and this goal has been supported by our substantial research and development investments. We spent approximately \$61.9 million in 2004, \$42.3 million in 2003 and

\$30.5 million in 2002 on research and development. We conduct research internally and also through collaborations with third parties, including universities, and we intend to maintain our strong commitment to our research and development efforts in the future. Approximately 36% of our research and development is conducted internally and 64% is conducted through collaborations with third parties, including contract research organizations and consultants.

### **Employees**

As of January 31, 2005, our workforce consisted of 134 full-time employees, 43 of whom hold Ph.D. or M.D. degrees, or both, and 30 of whom hold other advanced degrees. Of our total workforce, 102 are engaged in research and development and 32 are engaged in business development, finance and administration. None of our employees are represented by a collective bargaining agreement, nor have we experienced any significant work stoppages. We believe that our relations with our employees are good.

### **Available Information**

Our website address is [www.telik.com](http://www.telik.com); however, information found on, or that can be accessed through, our website is not incorporated by reference into this annual report. We file electronically with the SEC our annual report, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available free of charge on or through our website copies of these reports as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding our filings at [www.sec.gov](http://www.sec.gov).

### **Item 2. Properties.**

Our facility consists of approximately 92,000 square feet of research and office space located at 3165 Porter Drive in Palo Alto, California. The term of this lease is approximately 11.5 years, commencing in January 2003 and terminating in May 2014 with an option to extend the lease term for a period of five years. This facility replaced our previous research and office facility located at 750 Gateway Boulevard in South San Francisco, California, that expired in April 2003. In addition, we vacated approximately 7,000 square feet of office space located at 701 Gateway Boulevard that was leased to us until September 2004.

### **Item 3. Legal Proceedings.**

We are not currently involved in any material legal proceedings.

### **Item 4. Submission of Matters to a Vote of Security Holders.**

No matters were submitted to a vote of our stockholders during the fiscal quarter ended December 31, 2004.

## PART II

### Item 5. Market for Registrant's Common Equity and Related Stockholder Matters and Issuer Purchases of Equity Securities.

#### Market for Our Common Stock

Our common stock trades on the Nasdaq Stock Market under the symbol "TELK". The following table sets forth the high and low bid information for our common stock for each quarterly period within the two most recent fiscal years.

	<u>High</u>	<u>Low</u>
<b>2004</b>		
Quarter ended March 31, 2004 .....	\$28.69	\$22.40
Quarter ended June 30, 2004 .....	\$29.62	\$20.20
Quarter ended September 30, 2004 .....	\$23.89	\$15.08
Quarter ended December 31, 2004 .....	\$23.98	\$17.40
<b>2003</b>		
Quarter ended March 31, 2003 .....	\$13.60	\$10.02
Quarter ended June 30, 2003 .....	\$18.05	\$12.20
Quarter ended September 30, 2003 .....	\$23.25	\$15.55
Quarter ended December 31, 2003 .....	\$23.24	\$18.91

As of February 28, 2005 there were 117 stockholders of record. We have never paid our stockholders cash dividends, and we do not anticipate paying any cash dividends in the foreseeable future as we intend to retain any earnings for use in our business.

## Item 6. Selected Financial Data.

The following selected historical information has been derived from the audited financial statements of Telik. The financial information as of December 31, 2004 and 2003 and for each of the three years in the period ended December 31, 2004 are derived from audited financial statements included elsewhere in this Annual Report on Form 10-K. The following Selected Financial Data should be read in conjunction with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Item 8. Financial Statements and Supplementary Data" included elsewhere in this Annual Report on Form 10-K. The historical results are not necessarily indicative of the results of operations to be expected in the future.

	Years Ended December 31,				
	2004	2003	2002	2001	2000
	(In thousands, except per share amounts)				
<b>Statement of Operations Data:</b>					
Contract revenue from collaborations .....	\$ 163	\$ 436	\$ 1,245	\$ 1,788	\$ 2,721
Other revenues .....	—	—	42	83	75
	163	436	1,287	1,871	2,796
Operating costs and expenses:					
Research and development .....	61,868	42,311	30,549	18,174	10,450
General and administrative .....	10,613	9,915	6,665	4,278	6,340
Total operating costs and expenses .....	72,481	52,226	37,214	22,452	16,790
Loss from operations .....	(72,318)	(51,790)	(35,927)	(20,581)	(13,994)
Interest income, net .....	2,501	1,148	1,145	2,015	1,437
Net loss .....	(69,817)	(50,642)	(34,782)	(18,566)	(12,557)
Deemed dividend to preferred stockholders .....	—	—	—	—	(4,667)
Net loss allocable to common stockholders .....	<u>\$(69,817)</u>	<u>\$(50,642)</u>	<u>\$(34,782)</u>	<u>\$(18,566)</u>	<u>\$(17,224)</u>
Basic and diluted net loss per share .....	\$ (1.60)	\$ (1.38)	\$ (1.17)	\$ (0.77)	\$ (1.70)
Shares used to calculate basic and diluted net loss per share .....	43,701	36,812	29,786	24,030	10,128
Pro forma basic and diluted net loss per share* .....					\$ (0.94)
Shares used to calculate pro forma basic and diluted net loss per share* .....					18,254

\*Note: Our preferred stock was converted into common stock upon the closing of our initial public offering in August 2000. Pro forma net loss per share reflects the assumed conversion of our preferred stock into common stock at the beginning of year 2000.

	As of December 31,				
	2004	2003	2002	2001	2000
	(In thousands)				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents, investments and restricted investments .....	\$ 138,647	\$ 201,088	\$ 104,282	\$ 55,174	\$ 41,250
Working capital (a) .....	121,356	189,266	93,923	50,188	39,783
Total assets .....	146,133	208,307	108,973	57,315	42,994
Current portion of capital lease obligations and loans .....	1,339	907	124	—	—
Non-current portion of capital lease obligations, loans and long-term liabilities .....	1,029	1,493	303	—	69
Deferred stock compensation, net .....	—	(93)	(607)	(1,173)	(2,312)
Accumulated deficit .....	(237,748)	(167,931)	(117,289)	(82,507)	(63,941)
Total stockholders' equity .....	126,344	194,302	99,205	51,338	40,616

(a) Long-term investments for the years 2000 through 2003 have been reclassified to short-term investments to conform with our presentation in 2004. See Note 1 to Financial Statements.

## **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

### **Overview**

Telik is engaged in the discovery, development and commercialization of small molecule drugs. We have incurred net losses since inception and expect to incur substantial and increasing losses for the next several years as we expand our research and development activities and move our product candidates into later stages of development. As of December 31, 2004, we had an accumulated deficit of \$237.7 million.

Our expenses have consisted primarily of those incurred for research and development and general and administrative costs associated with our operations. The process of carrying out the development of our product candidates to later stages of development and our research programs may require significant additional research and development expenditures, including for preclinical testing and clinical trials, as well as for manufacturing development efforts and obtaining regulatory approval. We outsource our clinical trials and our manufacturing development activities to third parties to maximize efficiency and minimize our internal overhead. To date, we have funded our operations primarily through the sale of equity securities and non-equity payments from collaborative partners.

We are subject to risks common to biopharmaceutical companies, including risks inherent in our research, development and commercialization efforts, preclinical testing, clinical trials, uncertainty of regulatory and marketing approvals, enforcement of patent and proprietary rights, the need for future capital, potential competition, use of hazardous materials and retention of key employees. In order for a product to be commercialized, it will be necessary for us to conduct preclinical tests and clinical trials, demonstrate efficacy and safety of our product candidates to the satisfaction of regulatory authorities, obtain marketing approval, enter into manufacturing, distribution and marketing arrangements, obtain market acceptance and, in many cases, obtain adequate reimbursement from government and private insurers. We cannot provide assurance that we will generate revenues or achieve and sustain profitability in the future.

We expect that our quarterly and annual results of operations will fluctuate for the foreseeable future due to several factors, including the timing and extent of our research and development efforts and the outcome of our clinical trial activities. The successful development of our products is uncertain. Our limited operating history makes accurate prediction of future operating results difficult or impossible.

### *Clinical Status*

TELCYTA, our lead product candidate, is a small molecule tumor-activated cancer product candidate that we are evaluating initially to treat cancers that are resistant to standard chemotherapy drugs. We have three on-going Phase 3 registration trials with TELCYTA. The first Phase 3 clinical trial (ASSIST-1) is for the treatment of advanced ovarian cancer. The second Phase 3 clinical trial (ASSIST-2) is for the treatment of advanced non-small cell lung cancer. The third Phase 3 clinical trial (ASSIST-3) evaluates TELCYTA in combination with carboplatin for the treatment of second-line platinum resistant or refractory ovarian cancer.

In addition, in 2004 we initiated two Phase 2 clinical trials of TELCYTA for the treatment of Stage IIIb or IV non-small cell lung cancer for patients who have not previously received chemotherapy. One clinical trial is in combination with cisplatin, and the other clinical trial is in combination with carboplatin and paclitaxel. Platinum and taxane-based drug combinations are the current standard for the front-line chemotherapy of lung and ovarian cancer.

TELINTRA, our second product candidate, is a small molecule bone marrow stimulant we are developing for the treatment of blood disorders associated with low blood cell levels, such as neutropenia or anemia. Our Phase 2 clinical trial in patients with MDS, a pre-leukemic condition, is on-going and has not identified a dose limiting toxicity. MDS is a disease characterized by defects in the blood-producing cells of the bone marrow, in which low blood cell levels occur. We presented positive interim data at the American Society of Hematology

annual meeting in December 2004. In this study, clinically significant improvement was observed across all major MDS FAB subtypes and in all blood cell lineages. TELINTRA was well-tolerated in this predominantly elderly patient population, and enrollment is on-going.

We discovered all of our product candidates using our proprietary technology, Target-Related Affinity Profiling, or TRAP, which enables the rapid and efficient discovery of small molecule product candidates. We expect to enter into collaborative arrangements with third parties for clinical trials, development, manufacturing, regulatory approvals or commercialization of some of our products, particularly outside North America, or in disease areas requiring larger and longer clinical trials than cancer.

During 2004, we announced the following:

- Preclinical results that support advancement of TELCYTA clinical development to the front-line and second-line treatment settings. The data were presented at the American Association for Cancer Research 95th annual meeting.
- The initiation of a randomized Phase 3 registration trial of TELCYTA administered as a single agent in non-small cell lung cancer, or NSCLC, patients who have failed two prior chemotherapy regimens.
- The initiation of two Phase 2 clinical trials of TELCYTA for the treatment of Stage IIIB or IV non-small cell lung cancer for patients who have not previously received chemotherapy. One clinical trial is in combination with cisplatin, and the other clinical trial is in combination with carboplatin and paclitaxel.
- Positive results from three Phase 2 clinical trials testing TELCYTA in combination with approved chemotherapeutic drugs, including TELCYTA in combination with docetaxel in platinum resistant non-small cell lung cancer, TELCYTA in combination with carboplatin and TELCYTA in combination with Doxil in platinum refractory or resistant ovarian cancer at the American Society of Clinical Oncology annual meeting in June 2004. In October 2004, we announced additional positive data from the Phase 2 clinical trials of TELCYTA administered in combination with carboplatin and Doxil in platinum refractory or resistant ovarian cancer at the Tenth Biennial International Gynecologic Cancer Society meeting.
- The completion of enrollment for the ASSIST-1 clinical trial of TELCYTA, and the initiation of a new randomized Phase 3 clinical trial of TELCYTA called ASSIST-3, in second-line platinum refractory or resistant ovarian cancer.
- Positive interim data from the Phase 2 clinical trial of TELINTRA for the treatment of MDS. The data were reported in two presentations at the annual meeting of the American Society of Hematology in San Diego.
- The exercise by Hoffmann La-Roche of its option to select active lead compounds identified through its collaboration with us. To identify the lead compounds, we used our proprietary TRAP small molecule drug discovery technology to determine the molecules active against a disease target selected by Roche.
- The publication of a study in which our proprietary drug discovery technology, TRAP, was used to identify novel small molecule lead compounds using the "affinity fingerprints" of approved drugs with known activity against a selected biological target. The study was published in the Journal of Medicinal Chemistry.

#### **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an



on-going basis, we evaluate our estimates and judgments related to revenue recognition and clinical development costs. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 to our financial statements appearing at the end of this annual report, we believe the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements.

#### *Revenue recognition*

Since our inception, most of our revenues have been generated from license and research agreements with collaborators. We recognize cost reimbursement revenue under these collaborative agreements as the related research and development costs are incurred. We recognize milestone fees upon completion of specified milestones according to contract terms. Deferred revenue represents the portion of research payments received that has not been earned.

We also have royalty and licensing agreements with other pharmaceutical, biotechnology and genomics companies. Under these agreements, we may receive fees for collaborative research efforts, royalties on future sales of products, or some combination of these items. We recognize nonrefundable signing or license fees that are not dependent on future performance under these agreements as revenue when received or over the term of the arrangement if we have continuing performance obligations.

#### *Research and development expenses*

Our research and development expenses include salaries and benefits costs, fees for contractors, consultants and third-party contract research organizations and an allocation of facility and administrative costs. Research and development expenses consist of costs incurred for drug and product development, manufacturing, clinical activities, discovery research, screening and identification of product candidates, and preclinical studies. All such costs are charged to research and development expenses as incurred.

Clinical development costs are a significant component of research and development expenses. We have a history of contracting with third parties that perform various clinical trial activities on our behalf in the on-going development of our product candidates. The financial terms of these contracts are subject to negotiation and may vary from contract to contract and may result in uneven payment flows. We accrue and expense costs for clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with contract research organizations and clinical trial sites. We determine our estimates through discussion with internal clinical personnel and outside service providers as to progress or stage of completion of trials or services and the agreed upon fee to be paid for such services. These estimates may or may not match the actual services performed by the organizations as determined by patient enrollment levels and related activities. We monitor patient enrollment levels and related activities to the extent possible; however, if we underestimated activity levels associated with various studies at a given point in time, we could record significant research and development expenses in future periods.

### **Results of operations**

#### *Revenues*

	<u>Years Ended December 31,</u>			<u>Annual Percent Change</u>	
	<u>2004</u>	<u>2003</u>	<u>2002</u>	<u>2004/2003</u>	<u>2003/2002</u>
	(in thousands, except percentages)				
Revenues .....	\$ 163	\$436	\$1,287	(63)%	(66)%

Revenues in 2004 resulted from our collaborative agreement with Roche. Revenues in 2003 resulted primarily from our collaborative agreements with Sanwa and Roche, while revenues in 2002 included the collaborative agreement with Sanwa and funded research related to grants received from the National Institutes of Health, or NIH.

The decrease in revenues of 63%, or \$273,000, in 2004 compared to 2003 was the result of the following:

- \$417,000 due to the completion of the identification of a lead compound for Sanwa in 2003 and no further collaboration in 2004; and
- offset in part by a \$144,000 increase in revenue generated under our collaboration with Roche primarily due to the exercise by Roche of its option to select active lead compounds identified through its collaboration with us.

The decrease in revenues of 66%, or \$851,000, in 2003 compared to 2002 was the result of the following:

- \$828,000 due to the completion of the identification of a lead compound for Sanwa in May 2003;
- \$42,000 due to the completion of our research with the NIH in the second quarter of 2002 and no further research grants in 2003; and
- offset in part by \$19,000 generated under our collaboration with Roche in April 2003.

We expect near-term revenues to fluctuate primarily depending upon the extent to which we enter into new collaborative research agreements and the amounts of payments relating to such agreements.

#### *Research and development expenses*

Research and development expenses for the years ended December 31, 2004, 2003 and 2002 were \$61.9 million, \$42.3 million and \$30.5 million. Our research and development activities consist primarily of drug development, clinical supply manufacturing, clinical activities, discovery research, screening and identification of product candidates and preclinical studies. We group these activities into two major categories: "research and preclinical" and "clinical development."

The costs associated with research and preclinical and clinical development activities approximate the following:

	Years Ended December 31,			Annual Percent Change	
	2004	2003	2002	2004/2003	2003/2002
	(in thousands, except percentages)				
Research and preclinical .....	\$16,315	\$16,087	\$ 9,775	1%	65%
Clinical development .....	45,553	26,224	20,774	74%	26%
Total research and development .....	<u>\$61,868</u>	<u>\$42,311</u>	<u>\$30,549</u>	46%	39%

The increase of 46%, or \$19.6 million, in research and development expenses for the year ended December 31, 2004 compared to the same period in 2003 was principally due to the increased costs for the following:

- TELCYTA
  - costs associated with our Phase 3 registration trials in ovarian cancer and non-small cell lung cancer of approximately \$17.8 million;
  - approximately \$1.1 million for Phase 2 clinical trials costs in ovarian and lung cancer in combination with standard chemotherapy drugs; and
  - offset in part by a decrease of approximately \$2.7 million in drug supply manufacturing costs as a result of a decrease in drug substance production compared to 2003 and reduced development and analytical costs.

- TELINTRA
  - clinical drug supply manufacturing costs of approximately \$0.9 million due to the development of an oral formulation and continued production for our Phase 1-2 clinical trial for the treatment of MDS.
- Other expenses
  - approximately \$3.6 million associated with headcount growth and increased expenses to support clinical activities.

The increase of 39%, or \$11.8 million, in research and development expenses for the year ended December 31, 2003 compared to the same period in 2002 was principally due to the increased costs for the following:

- TELCYTA
  - costs associated with the initiation of our Phase 3 registration trial in ovarian cancer of \$7.8 million;
  - net decrease of \$757,000 in costs due to the wind down of Phase 2 single agent clinical trials in ovarian, lung and breast cancer and completion of the Phase 1 advanced cancer clinical trial, offset by additional costs associated with Phase 1-2 clinical trials in ovarian and lung cancer in combination with standard chemotherapy drugs; and
  - offset in part by a decrease of approximately \$2.3 million in drug supply costs as a result of cost reductions due to manufacturing efficiencies, offset in part by purchases of the comparator drug, Iressa.
- TELINTRA
  - decrease in clinical drug supply manufacturing costs of approximately \$1.3 million due to adequate drug supplies.
- Other expenses
  - higher facility and information technology related cost allocations of approximately \$5.0 million primarily as a result of increased laboratory space in our Palo Alto facility; and
  - approximately \$2.7 million associated with headcount growth and increased expenses to support clinical activities.

We expect research and development expenditures to increase in the future as a result of increased manufacturing and clinical development costs primarily relating to our TELCYTA and TELINTRA product candidates development. The timing and the amount of these expenditures will depend upon the outcome of our on-going clinical trials, the costs associated with the Phase 3 clinical trials of TELCYTA, including related expansion of our research and development organization, regulatory requirements, advancement of our preclinical programs and product manufacturing costs.

The following table summarizes our principal product development initiatives, including the related stages of development for each product in development and the research and development expenses recognized in connection with each product. The information in the column labeled "Estimated Completion of Current Phase" is our current estimate of the timing of completion of enrollment. The actual timing of completion of enrollment could differ materially from the estimates provided in the table. For a discussion of the risks and uncertainties associated with the timing of completing a product development phase, see the risk factors "All of our product candidates are in research and development. If clinical trials of TELCYTA and TELINTRA are delayed or unsuccessful or if we are unable to complete the preclinical development of our other preclinical product candidates, our business may suffer," "If we do not obtain regulatory approval to market products in the United States and foreign countries, we or our collaborators will not be permitted to commercialize our product

candidates,” “As our product programs advance, we will need to hire additional scientific and management personnel. Our research and development efforts will be seriously jeopardized if we are unable to attract and retain key personnel,” and “If we are unable to enter into or maintain existing contracts with third parties to manufacture our product candidates or any products that we may develop in sufficient quantities and at an acceptable cost, clinical development of product candidates could be delayed and we may be unable to meet demand for any products that we may develop and lose potential revenue” sections of “Risk Factors” below.

Product	Description	Phase of Development	Estimated Completion or Completion of Phase	Related R&D Expenses Years Ended December 31,		
				2004	2003	2002
				(in thousands)		
TELCYTA				\$44,109	\$26,136	\$17,435
	Ovarian	Phase 3	2005			
	Non-small cell lung	Phase 3	2005			
	Ovarian, 2 <sup>nd</sup> line	Phase 3	2005			
	Combination (with other drugs)	Phase 2	2005			
	Ovarian	Phase 2	2004			
	Lung	Phase 2	2004			
	Breast	Phase 2	2004			
	Colorectal	Phase 2	2003			
	Advanced cancers	Phase 1	2002			
TELINTRA	Myelodysplastic syndrome	Phase 1-2	2005	3,654	2,688	3,810
Other (1)				<u>14,105</u>	<u>13,487</u>	<u>9,304</u>
	Total research and development expenses			\$61,868	\$42,311	\$30,549

- (1) “Other” constitutes research and development activities performed by our Chemistry, Biology, preclinical and Quality Assurance departments as these costs cannot be allocated to any individual project.

The largest component of our total operating expenses is our on-going investments in our research and development activities and, in particular, the clinical development of our product candidate pipeline. The process of conducting the clinical research necessary to obtain FDA approval is costly and time consuming. Current FDA requirements for a new human drug to be marketed in the United States include:

- the successful conclusion of preclinical laboratory and animal tests, if appropriate, to gain preliminary information on the product’s safety;
- filing with the FDA of an IND, to conduct initial human clinical trials for drug candidates;
- the successful completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product; and
- filing by company and acceptance and approval by the FDA of a New Drug Application for a product candidate to allow commercial distribution of the drug.

In view of the factors mentioned above, we consider the active management and development of our clinical pipeline to be crucial to our long-term success. The actual probability of success for each candidate and clinical program may be impacted by a variety of factors, including, among others, the quality of the candidate, the validity of the target and disease indication, early clinical data, investment in the program, competition,

manufacturing capability and commercial viability. Due to these and other factors, it is difficult to give accurate guidance on the anticipated proportion of our research and development investments or the future cash inflows from these programs.

#### *General and administrative expenses*

	<u>Years Ended December 31,</u>			<u>Annual Percent Change</u>	
	<u>2004</u>	<u>2003</u>	<u>2002</u>	<u>2004/2003</u>	<u>2003/2002</u>
	(in thousands, except percentages)				
General and administrative .....	\$10,613	\$9,915	\$6,665	7%	49%

The increase of 7%, or \$698,000, in general and administrative expenses in 2004 compared to 2003 was due primarily to increased costs for the following:

- approximately \$1.3 million in marketing expenses due to increased marketing program activities for TELCYTA; and
- offset in part by decreased outside legal fees of approximately \$742,000.

The increase of 49%, or \$3.3 million, in general and administrative expenses in 2003 compared to 2002 was due primarily to increased costs for the following:

- approximately \$2.4 million in costs associated with headcount growth and increased expenses necessary to manage the growth of our operations;
- additional rent and related facility costs associated with our Palo Alto facility effective January 2003 of approximately \$686,000; and
- lease exit cost of approximately \$206,000 associated with our South San Francisco office space.

We expect future general and administrative expenses to increase in support of expanded business activities including costs associated with our marketing efforts to support our commercialization strategy for TELCYTA.

#### *Interest income and interest expense*

	<u>Years Ended December 31,</u>			<u>Annual Percent Change</u>	
	<u>2004</u>	<u>2003</u>	<u>2002</u>	<u>2004/2003</u>	<u>2003/2002</u>
	(in thousands, except percentages)				
Interest Income .....	\$2,702	\$1,303	\$1,161	107%	12%
Interest Expense .....	\$ 201	\$ 155	\$ 16	30%	869%

Interest income of \$2.7 million, \$1.3 million and \$1.2 million for the years ended December 31, 2004, 2003 and 2002 resulted primarily from earnings on investments. The increase in net interest income of \$1.4 million in 2004 compared to 2003 was due to higher average interest rates in 2004 and higher principal balance of our investments for the full year as a result of \$142.8 million in net proceeds obtained from our follow-on offering in November 2003. The increase in net interest income of \$142,000 in 2003 compared to 2002 was due to higher principal balance of our investments as a result of our follow-on offering in November 2003, offset in part by lower average interest rates in 2003.

Interest expense was \$201,000, \$155,000 and \$16,000 for the years ended December 31, 2004, 2003 and 2002. The increase in interest expense in 2004 compared to 2003 and from 2003 compared to 2002 were due primarily to our borrowings under the capital lease and equipment loan facilities. We expect interest expenditures to decrease in the future as we pay down our lease and loan obligations.

## Liquidity and capital resources

	2004	2003	2002
	(In millions, except ratios)		
<b>December 31:</b>			
Cash, cash equivalents, investments and restricted cash	\$138.6	\$ 201.1	\$104.3
Working capital	\$121.4	\$ 189.3	\$ 93.9
Current ratio	7.9 : 1	17.0 : 1	10.9 : 1

### Year ended December 31:

Cash provided by (used in):			
Operating activities	\$(62.7)	\$ (45.4)	\$(32.1)
Investing activities	\$ 40.3	\$ (58.6)	\$(55.0)
Financing activities	\$ 1.8	\$ 146.2	\$ 82.2
Capital expenditures (included in investing activities above)	\$ (1.3)	\$ (4.0)	\$ (1.1)

*Sources and Uses of Cash.* Due to the significant research and development expenditures and the lack of any approved products to generate revenue, we have not been profitable and have generated operating losses since we incorporated in 1988. As such, we have funded our research and development operations through sales of equity, collaborative arrangements with corporate partners, interest earned on investments and equipment lease financings. At December 31, 2004, we had available cash, cash equivalents, investments and restricted investments of \$138.6 million. Our cash and investment balances are held in a variety of interest-bearing instruments including obligations of U.S. government agencies, high-grade corporate and municipal bonds, commercial paper and money market accounts. Cash in excess of immediate requirements is invested with regard to liquidity and capital preservation. Wherever possible, we seek to minimize the potential effects of concentration and degrees of risk.

*Cash Flows from Operating Activities.* Cash used in operations for 2004 was \$62.7 million compared with \$45.4 million in 2003 and \$32.1 million in 2002. The net loss of \$69.8 million in 2004 included non-cash charges of \$1.4 million for depreciation and amortization, \$93,000 for the amortization of deferred stock compensation and \$197,000 related to non-cash stock based compensation to non employees. Cash used in operations was offset by \$2.1 million in accounts payable and \$3.7 million in accrued liabilities primarily due to expenses related to our Phase 3 clinical trials in ovarian and non-small cell lung cancers. Cash used in operations in 2003 resulted from the net loss of \$50.6 million which included non-cash charges of \$1.1 million for depreciation and amortization, \$419,000 for the amortization of deferred stock compensation and \$266,000 related to non-cash stock based compensation to non employees. Cash usage in 2003 was further impacted by \$3.6 million in accounts payable and \$420,000 in prepaid expenses due to the increase in operating expense levels. Cash used in operations was offset by \$1.7 million received from our landlord to fund leasehold improvements, \$3.3 million in accrued clinical trial expenses mainly from our Phase 3 clinical trial in ovarian cancer and \$1.9 million in accrued compensation and vacation liabilities from additional personnel added during the year. Operating cash used in 2002 resulted primarily from our net loss of \$34.8 million which included \$1.3 million in non-cash charges for depreciation expense, deferred stock compensation, stock based compensation expense and loan forgiveness. In addition cash usage was further impacted by \$1.7 million in receivable from our landlord for leasehold improvements, offset by increases of \$2.9 million in accounts payable and accrued liabilities related to research and development activities and \$705,000 related to accrued compensation.

*Cash Flows from Investing Activities.* Cash provided in investing activities for 2004 was \$40.3 million compared to cash used of \$58.6 million in 2003 and \$55.0 million in 2002. Cash was provided in 2004 by \$175.9 million from sales and maturities of investments offset by \$134.4 million in purchases of investment securities. Capital expenditures for 2004 were \$1.3 million primarily for laboratory and computer equipment purchases. Investing activities in 2003 were primarily related to \$164.5 million in purchases of short-term available-for-sale investments offset by \$107.9 million in sales and maturities of investments. Cash used in investing activities in

2003 was further impacted by purchases of property and equipment of \$4.0 million primarily due to leasehold improvements on our Palo Alto facility and laboratory equipment expenditures, offset by a reduction in restricted investments by \$2.0 million for the portion of tenant improvements completed on the Palo Alto facility that no longer require a security deposit. Cash used in 2002 was related to \$50.0 million in net purchases of investments, \$3.8 million in restricted cash for a security deposit on our Palo Alto facility and \$1.1 million laboratory equipment purchases.

*Cash Flows from Financing Activities.* Cash provided by financing activities for 2004 was approximately \$1.8 million compared with \$146.2 million in 2003 and \$82.2 million in 2002. Cash provided in 2004 from financing activities of \$1.8 million was primarily from our stock option exercises and stock purchase plan. Financing activities in 2003 included approximately \$142.8 million in net proceeds from our follow-on public offering of common stock completed in December, \$2.2 million from our stock option exercises and stock purchase plan and \$1.7 million obtained through capital loans. Cash provided by financing activities in 2003 was offset in part by \$548,000 in payments under capital leases and loans. Financing activities in 2002 included approximately \$80.3 million in net proceeds from the sale of our common stock in a follow-on public offering in October and \$1.6 million from our stock option exercises and stock purchase plan.

*Working Capital.* Working capital decreased to \$121.4 million at December 31, 2004 from \$189.3 million at December 31, 2003. The decrease in working capital was primarily due our use of cash in operations due to the expansion of our TELCYTA development program and costs associated with headcount growth.

In August 2003, we obtained a \$1.5 million equipment loan facility from a banking institution, secured by equipment purchased. At December 31, 2004, draws under this credit facility totaled approximately \$1.5 million and no further borrowings are available.

In February 2005, we completed a follow-on public offering of 8,050,000 shares of common stock, including shares issued in connection with the underwriters' exercise of their over-allotment option, at a price of \$18.75 per share, raising net proceeds of approximately \$142.6 million after deducting underwriters' discounts and commissions.

We believe our existing cash resources, together with the net proceeds from our follow-on offering in February 2005 will be sufficient to satisfy our current operating plan at least until the end of 2006. We expect the increase in clinical development expenses as a result of Phase 3 clinical trials to consume a large portion of our existing cash resources. Changes in our research and development plans or other changes affecting our operating expenses may affect actual future consumption of existing cash resources as well. In any event, we will require substantial additional financing to fund our operations in the future. We may seek to raise any necessary additional funds through equity or debt financings, collaborative arrangements with corporate partners or other sources. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience dilution. Debt financing may subject us to restrictive covenants that may adversely affect our operations. To the extent that we raise additional capital through licensing arrangements or arrangements with collaborative partners, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize ourselves. Our future capital uses and requirements depend on numerous factors, including the following:

- the progress and success of preclinical studies and clinical trials of our product candidates;
- the progress and number of research programs in development;
- the costs associated with conducting Phase 3 clinical trials;
- the costs and timing of obtaining regulatory approvals;
- our ability to establish, and the scope of, any new collaborations;
- our ability to meet the milestones identified in our collaborative agreements that trigger payments;

- the costs and timing of obtaining, enforcing and defending our patent and intellectual property rights;
- competing technological and market developments; and
- the timing and scope of commercialization expenses for our product candidates as they approach regulatory approval.

We currently have no commitments for any additional financings. If we need to raise additional money to fund our operations, funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may not be able to market our products as planned or continue development of our products, or we could be required to delay, scale back or eliminate some or all of our research and development programs.

Our future contractual obligations at December 31, 2004 are as follows:

	<u>Total</u>	<u>2005</u>	<u>2006-2007</u>	<u>2008-2009</u>	<u>After 2009</u>
			(In thousands)		
Capital lease obligations .....	\$ 564	\$ 318	\$ 246	\$ —	\$ —
Equipment loans .....	1,972	1,151	821	—	—
Operating leases .....	35,532	5,268	6,687	7,071	16,506
Total contractual cash obligations .....	<u>\$38,068</u>	<u>\$6,737</u>	<u>\$7,754</u>	<u>\$7,071</u>	<u>\$16,506</u>

We have a contractual obligation under the terms of our manufacturing supply agreement with Organichem Corporation, wherein we are obligated to purchase a significant percentage of our United States requirements for the active ingredient in TELCYTA for a number of years. We have agreed on a pricing schedule for such supply, which will be subject to future renegotiation after a defined time period.

#### Recent Accounting Pronouncements

In March 2004, the FASB approved Emerging Issues Task Force (EITF) Issue No. 03-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments." The objective of this issue is to provide guidance for identifying other-than-temporarily impaired investments. EITF No. 03-1 also provides new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB issued EITF No. 03-1-1, which delayed the effective date of EITF No. 03-1, with the exception of certain disclosure requirements. We do not believe that the adoption of EITF No. 03-1 will have a material impact on our financial condition and results of operations.

In December 2004, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards 123R (SFAS123R), "Share-Based Payment—An Amendment of FASB Statements No. 123 and 95, which eliminated the ability to account for share-based compensation transactions using Accounting Principles Board Opinion No. 25 (APB 25), "Accounting for Stock Issued to Employees." SFAS 123R will instead require companies to recognize compensation expense, using a fair-value based method, for costs related to share-based payments including stock options and employee stock purchase plans. SFAS 123R is effective for public companies in periods beginning after June 15, 2005. We will be required to implement the standard no later than the quarter that begins July 1, 2005. The cumulative effect of adoption, if any, applied on a modified prospective basis, would be measured and recognized on July 1, 2005. The adoption of FAS 123R and other potential changes will materially impact our results of operations. We are in the process of evaluating which method we will adopt in the expensing of employee stock options.



## RISK FACTORS

*You should carefully consider these risk factors as each of these risks could adversely affect our business, operating results and financial condition.*

**We have a history of net losses, which we expect to continue for at least several years. We will never be profitable unless we develop, and obtain regulatory approval and market acceptance of, our product candidates.**

Due to the significant research and development expenditures required to develop our TRAP technology and identify new product candidates, and the lack of any products to generate revenue, we have not been profitable and have incurred operating losses since we were incorporated in 1988. As of December 31, 2004, we had an accumulated deficit of \$237.7 million. We expect to incur losses for at least the next several years and expect that these losses will increase as we expand our research and development activities and incur significant clinical testing costs. We do not anticipate that we will generate product revenue for several years. Our losses, among other things, have caused and will cause our stockholders' equity and working capital to decrease. To date, we have derived substantially all of our revenues, which have not been significant, from project initiation fees and research reimbursement paid pursuant to existing collaborative agreements with third parties and achievement of milestones under current collaborations. We expect that this trend will continue until we develop, and obtain regulatory approval and market acceptance of, our product candidates, if at all. We may never generate product revenue sufficient to become profitable.

**All of our product candidates are in research and development. If clinical trials of TELCYTA or TELINTRA are delayed or unsuccessful or if we are unable to complete the preclinical development of our other preclinical product candidates, our business may suffer.**

Preclinical testing and clinical trials are long, expensive and uncertain processes. It may take us or our collaborators several years to complete this testing, and failure can occur at any stage of the process. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of clinical trials do not necessarily predict final results. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier clinical trials.

TELCYTA has to date been evaluated in Phase 1 and Phase 2 clinical trials. We initiated a Phase 3 registration trial of TELCYTA in ovarian cancer in the first quarter of 2003, a Phase 3 registration trial of TELCYTA in non-small cell lung cancer in March 2004 and a Phase 3 registration trial of TELCYTA in combination with carboplatin versus Doxil as second-line therapy in platinum refractory or resistant ovarian cancer in December 2004. These clinical trials test TELCYTA against a control arm consisting of currently established standard drug treatments for these cancers. Changes in standards of care during our Phase 3 clinical trials may cause us to, or the FDA may require us to perform additional clinical testing of TELCYTA against a different control arm prior to filing a New Drug Application for marketing approval. AstraZeneca, the manufacturer of Iressa, recently announced that studies indicate that while Iressa appears to benefit some patients, it does not significantly prolong survival in the overall population of patients using the drug. Should the FDA undertake any action based on these studies, such as instructing us to suspend our Phase 3 clinical trial of TELCYTA in non-small cell lung cancer, which utilizes Iressa as a comparator drug, our ability to complete the clinical trial could be compromised. As a result, we may not be able to gain the FDA's approval for the use of TELCYTA in non-small cell lung cancer based on this Phase 3 clinical trial, or approval of this indication could be delayed.

We are also currently in a Phase 2 clinical trial of TELINTRA in MDS, a form of pre-leukemia, to evaluate safety, pharmacokinetics, pharmacodynamics and efficacy. Our success also depends, in part, on our ability to complete clinical development of TELINTRA or other preclinical product candidates and take them through early clinical trials.

Any clinical trial may fail to produce results satisfactory to the FDA. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be repeated or a program to be terminated. We typically rely on third-party clinical investigators to conduct our clinical trials and, as a result, we may face additional delays outside our control. We have engaged contract research organizations, or CROs, to facilitate the administration of our Phase 3 clinical trials of TELCYTA. Dependence on a CRO subjects us to a number of risks. Delays in identifying and engaging a CRO may result in delays in the initiation of other clinical trials. We may not be able to control the amount and timing of resources the CRO may devote to our clinical trials. Should the CRO fail to administer our Phase 3 clinical trials properly, regulatory approval, development and commercialization of TELCYTA will be delayed.

We do not know whether we will begin planned clinical trials on time or whether we will complete any of our on-going clinical trials on schedule, if at all. We do not know whether any clinical trials will result in marketable products. Typically, there is a high rate of failure for product candidates in preclinical and clinical trials. We do not anticipate that any of our product candidates will reach the market for several years.

Significant delays in clinical testing could materially impact our clinical trials. We do not know whether planned clinical trials will begin on time, will need to be revamped or will be completed on schedule, if at all. In addition to the reasons stated above, clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a study, delays in reaching agreement on acceptable clinical study agreement terms with prospective clinical sites, delays in obtaining institutional review board approval to conduct a study at a prospective clinical site and delays in recruiting subjects to participate in a study.

Delays can also materially impact our product development costs. If we experience delays in testing or approvals, our product development costs will increase. For example, we may need to make additional payments to third-party investigators and organizations to retain their services or we may need to pay recruitment incentives. If the delays are significant, our financial results and the commercial prospects for our product candidates will be harmed, and our ability to become profitable will be delayed.

**We believe that our ability to compete depends, in part, on our ability to use our proprietary TRAP technology to discover new pharmaceutical products.**

TRAP, our proprietary drug discovery technology, is a relatively new drug discovery method that uses a protein panel of approximately 20 proteins selected for their distinct patterns of interacting with small molecules. This panel may lack essential types of interactions that we have not yet identified, which may result in our inability to identify active compounds that have the potential for us to develop into commercially viable drugs.

**If we are unable to raise adequate funds in the future, we will not be able to continue to fund our operations, research programs, preclinical testing and clinical trials to develop our product candidates.**

The process of carrying out the development of our own unpartnered product candidates to later stages of development and developing other research programs to the stage that they may be partnered will require significant additional expenditures, including the expenses associated with preclinical testing, clinical trials and obtaining regulatory approval. We believe that our existing cash and investment securities, together with the proceeds of from our follow-on offering in February 2005, will be sufficient to support our current operating plan at least until the end of 2006. Changes in our research and development plans or other changes affecting our operating expenses may affect actual future consumption of existing cash resources as well. In any event, we will require substantial additional financing to fund our operations in the future. We do not know whether additional financing will be available when needed or that, if available, we will obtain financing on terms favorable to our stockholders. As of December 31, 2004, our accumulated deficit was \$237.7 million, and we expect capital outlays and operating expenditures to increase over the next several years as we expand our clinical, research and development activities. The extent of any actual increase in operating or capital spending will depend in part on

the clinical success of our product candidates. If we fail to raise adequate funds on terms acceptable to us, if at all, we will not be able to continue to fund our operations, research programs, preclinical testing and clinical trials.

**Raising additional capital by issuing securities or through collaboration and licensing arrangements may cause dilution to existing stockholders or require us to relinquish rights to our technologies or product candidates.**

We may seek to raise any necessary additional funds through equity or debt financings, collaborative arrangements with corporate partners or other sources. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience dilution. To the extent that we raise additional capital through licensing arrangements or arrangements with collaborative partners, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize ourselves.

**If our competitors develop and market products that are more effective than our product candidates or any products that we may develop, or obtain marketing approval before we do, our commercial opportunity will be reduced or eliminated.**

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Some of the drugs that we are attempting to develop, such as TELINTRA, will have to compete with existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies in the United States and abroad. Our competitors may develop new screening technologies and may utilize discovery techniques or partner with collaborators in order to develop products more rapidly or successfully than we or our collaborators are able to do.

Many of our competitors, particularly large pharmaceutical companies, have substantially greater financial, technical and human resources than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures, licensing arrangements or other collaborations. In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competing products or technologies and may establish exclusive collaborative or licensing relationships with our competitors.

Our competitors may succeed in developing technologies and drugs that are more effective, better tolerated or less costly than any which are being developed by us or which would render our technology and potential drugs obsolete and noncompetitive. In addition, our competitors may succeed in obtaining FDA or other regulatory approvals for product candidates more rapidly than us or our collaborators. Any drugs resulting from our research and development efforts, or from our joint efforts with our existing or future collaborative partners, may not be able to compete successfully with our competitors' existing products or products under development or may not obtain regulatory approval in the United States or elsewhere.

**If we do not obtain regulatory approval to market products in the United States and foreign countries, we or our collaborators will not be permitted to commercialize our product candidates.**

Even if we are able to achieve success in our preclinical testing, we, or our collaborators, must provide the FDA and foreign regulatory authorities with clinical data that demonstrate the safety and efficacy of our product candidates in humans before they can be approved for commercial sale. Failure to obtain regulatory approval will prevent commercialization of our product candidates.

The pharmaceutical industry is subject to stringent regulation by a wide range of authorities. We cannot predict whether regulatory clearance will be obtained for any product candidate that we are developing or hope to

develop. A pharmaceutical product cannot be marketed in the United States until it has completed rigorous preclinical testing and clinical trials and an extensive regulatory clearance process implemented by the FDA. Satisfaction of regulatory requirements typically takes many years and depends on the type, complexity and novelty of the product and requires the expenditure of substantial resources. Of particular significance are the requirements covering research and development, testing, manufacturing, quality control, labeling and promotion of drugs for human use.

Before commencing clinical trials in humans, we, or our collaborators, must submit and receive approval from the FDA of an IND application. We must comply with FDA "Good Laboratory Practices" regulations in our preclinical studies. Clinical trials are subject to oversight by institutional review boards of participating clinical sites and the FDA and:

- must be conducted in conformance with the FDA regulations;
- must meet requirements for institutional review board approval;
- must meet requirements for informed consent;
- must meet requirements for Good Clinical Practices;
- may require large numbers of participants; and
- may be suspended by us, our collaborators or the FDA at any time if it is believed that the subjects participating in these trials are being exposed to unacceptable health risks or if the FDA finds deficiencies in the IND application or the conduct of these trials.

Before receiving FDA clearance to market a product, we or our collaborators must demonstrate that the product candidate is safe and effective in the patient population that will be treated. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be repeated, a program to be terminated and could delay approval. We typically rely on third-party clinical investigators to conduct our clinical trials and other third party organizations to perform data collection and analysis and, as a result, we may face additional delaying factors outside our control. In addition, we may encounter delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy or interpretation during the period of product development, clinical trials and FDA regulatory review. Failure to comply with applicable FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other regulatory action. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval.

If regulatory clearance of a product is granted, this clearance will be limited to those disease states and conditions for which the product is demonstrated through clinical trials to be safe and efficacious, which could limit our market opportunity. Furthermore, product approvals, once granted, may be withdrawn if problems occur after initial marketing. We cannot ensure that any compound developed by us, alone or with others, will prove to be safe and efficacious in clinical trials and will meet all of the applicable regulatory requirements needed to receive marketing clearance. Regulatory clearance may also contain requirements for costly post-marketing testing and surveillance to monitor the safety and efficacy of the product. If problems occur after initial marketing, such as the discovery of previously unknown problems with our product candidates, including unanticipated adverse events or adverse events of unanticipated severity or frequency, or manufacturer or manufacturing issues, marketing approval can be withdrawn.

Outside the United States, the ability to market a product depends on receiving a marketing authorization from the appropriate regulatory authorities. This foreign regulatory approval process typically includes all of the risks associated with FDA clearance described above and may include additional risks.

**As our product programs advance, we will need to hire additional scientific and management personnel. Our research and development efforts will be seriously jeopardized if we are unable to attract and retain key personnel.**

Our success depends in part on the continued contributions of our principal management and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, scientists and companies in the face of intense competition for such personnel. As we plan for and commence additional advanced clinical trials, including Phase 2 and Phase 3, we will also need to expand our clinical development personnel. In addition, our research programs depend on our ability to attract and retain highly skilled chemists and other scientists. None of our key employees have indicated to Telik that they have plans to retire or leave Telik in the near future. If we lose the services of Dr. Wick or any of our other key personnel, our research and development efforts could be seriously and adversely affected. We have generally entered into consulting or other agreements with our scientific and clinical collaborators and advisors. We do not carry key person insurance that covers Dr. Wick or any of our other key employees. There is currently a shortage of skilled executives and employees with technical expertise in the biotechnology industry, and this shortage is likely to continue. As a result, competition among numerous companies, academic and other research institutions for skilled personnel and experienced scientists is intense and turnover rates are high. The cost of living in the San Francisco Bay Area is very high compared to other parts of the country, which we expect will adversely affect our ability to compete for qualified personnel and will increase costs. Because of this competitive environment, we have encountered and may continue to encounter increasing difficulty in attracting qualified personnel as our operations expand and the demand for these professionals increases, and this difficulty could significantly impede the achievement of our research and development objectives.

**If physicians and patients do not accept products that we may develop, our ability to generate product revenue in the future will be adversely affected.**

Products that we may develop may not gain market acceptance among physicians, healthcare payors, patients and the medical community. Market acceptance of and demand for any products that we may develop will depend on many factors, including the following:

- our ability to provide acceptable evidence of safety and efficacy;
- convenience and ease of administration;
- cost effectiveness;
- the effectiveness of our marketing strategy and the pricing of any products that we may develop;
- our ability to obtain third-party coverage or reimbursement; and
- the prevalence and severity of adverse side effects.

Physicians may elect not to recommend products that we may develop even if we meet the above criteria. If any product that we may develop fails to achieve market acceptance, we may not be able to successfully market and sell the product, which would limit our ability to generate revenue and adversely affect our operations.

**If we or our licensees cannot obtain and defend our respective intellectual property rights, or if our product candidates, technologies or any products that we may develop are found to infringe patents of third parties, we could become involved in lengthy and costly legal proceedings that could adversely affect our business.**

Our success will depend in a large part on our own and our licensees' ability to obtain and defend patents for each party's respective technologies and the compounds and other products, if any, resulting from the application of these technologies. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. As a result, the degree of future protection for our proprietary rights is uncertain, and we cannot assure you that:

- we were the first to make the inventions covered by each of our pending patent applications;

- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our pending patent applications will result in issued patents;
- any patents issued to us or our collaborators will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- any of our issued patents will be valid or enforceable; or
- we will develop additional proprietary technologies that are patentable.

Accordingly, we cannot predict the breadth of claims allowed in our or other companies' patents.

For TRAP, we hold patents in the United States and internationally, including a pending foreign application. These patents, and any patent that may issue on the pending application, will expire between 2014 and 2015. For TELCYTA, we hold compound patents in the United States and internationally, including a pending foreign application. These patents, and any patent that may issue on the pending application, will expire in 2013 and 2014. For TELINTRA, we hold compound patents in the United States and internationally, including a pending foreign application. These patents, and any patent that may issue on the pending application, will expire in 2014. We can generally apply for patent term extensions on the patents for TELCYTA and TELINTRA when and if marketing approvals for these compounds are obtained in the relevant countries.

Our success will also depend, in part, on our ability to operate without infringing the intellectual property rights of others. We cannot assure you that our activities will not infringe patents owned by others. As of the date of this annual report, we have not received any communications with the owners of related patents alleging that our activities infringe their patents. However, if our product candidates, technologies or any products that we may develop are found to infringe patents issued to third parties, the manufacture, use and sale of any products that we may develop could be enjoined, and we could be required to pay substantial damages. In addition, we may be required to obtain licenses to patents or other proprietary rights of third parties. We cannot assure you that any licenses required under any such patents or proprietary rights would be made available on terms acceptable to us, if at all. Failure to obtain such licenses could negatively affect our business.

Others may have filed and in the future may file patent applications covering small molecules or therapeutic products that are similar to ours. We cannot assure you that our patent applications will have priority over patent applications filed by others. Any legal action against us or our collaborators claiming damages and seeking to enjoin commercial activities relating to the affected products and processes could, in addition to subjecting us to potential liability for damages, require us or our collaborators to obtain a license to continue to manufacture or market the affected products and processes. We cannot predict whether we, or our collaborators, would prevail in any of these actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. We believe that there may be significant litigation in the industry regarding patent and other intellectual property rights. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, and we may not be successful in any such litigation.

In addition, we could incur substantial costs and use of our key employees' time and efforts in litigation if we are required to defend against patent suits brought by third parties or if we initiate these suits, and we cannot predict whether we would be able to prevail in any of these suits.

Furthermore, some of our patents and intellectual property rights are owned jointly by us and our collaborators. While there are legal and contractual restraints on the rights of these joint owners, they may use these patents and other intellectual property in ways that may harm our business. We may not be able to prevent this type of use.

We also rely on trade secrets to protect technology, including aspects of our TRAP technology, where we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, academic collaborators and consultants to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If the identity of specific proteins or other elements of our TRAP technology become known, our competitive advantage in drug discovery could be reduced.

Many of our collaborators and scientific advisors have publication and other rights to certain information and data gained from their collaboration and research with us. Any publication or other use could limit our ability to secure intellectual property rights or impair any competitive advantage that we may possess or realize by maintaining the confidentiality of the information or data.

**We will depend on collaborative arrangements to complete the development and commercialization of some of our product candidates. These collaborative arrangements may place the development of our product candidates outside of our control, may require us to relinquish important rights or may otherwise not be on terms favorable to us.**

We expect to enter into collaborative arrangements with third parties for clinical trials, development, manufacturing, regulatory approvals or commercialization of some of our product candidates, particularly outside North America, or in disease areas requiring larger and longer clinical trials. Dependence on collaborative arrangements will subject us to a number of risks. We may not be able to control the amount and timing of resources our collaborative partners may devote to the product candidates. Our collaborative partners may experience financial difficulties. Should a collaborative partner fail to develop or commercialize a compound or product candidate to which it has rights from us, we may not receive any future milestone payments and will not receive any royalties for this compound or product candidate. Business combinations or significant changes in a collaborative partner's business strategy may also adversely affect a partner's willingness or ability to complete its obligations under the arrangement. If we fail to enter into additional collaborative agreements on favorable terms, our business, financial condition and results of operations could be materially adversely affected.

Some of our collaborations are for early stage programs and allow partners significant discretion in electing whether to pursue any of the planned activities. We do not anticipate significant revenues to result from these relationships until the collaborator has advanced product candidates into clinical trials, which will not occur for several years, if at all. These arrangements are subject to numerous risks, including the right of the collaboration partner to control the timing of the research and development efforts, the advancement of lead product candidates to clinical trials and the commercialization of product candidates. In addition, a collaborative partner could independently move forward with a competing lead candidate developed either independently or in collaboration with others, including our competitors.

**If we are unable to enter into or maintain existing contracts with third parties to manufacture our product candidates or any products that we may develop in sufficient quantities and at an acceptable cost, clinical development of product candidates could be delayed and we may be unable to meet demand for any products that we may develop and lose potential revenue.**

We do not currently operate manufacturing facilities for clinical or commercial production of our product candidates. We expect to continue to rely on third parties for the manufacture of our product candidates and any products that we may develop. We currently lack the resources and capability to manufacture any of our product candidates on a clinical scale or any products that we may develop on a commercial scale. As a result, we will be dependent on corporate partners, licensees or other third parties for the manufacturing of clinical and commercial scale quantities of our product candidates and any products that we may develop. Our product candidates and any products that we may develop may be in competition with other product candidates and products for access to these facilities. For this and other reasons, our collaborators or third parties may not be able to manufacture these

product candidates and products in a cost effective or timely manner. While we currently possess sufficient inventory of TELCYTA and TELINTRA that are stored in multiple locations and an additional, substantial quantity of the active ingredient in TELCYTA, if these inventories are lost or damaged, the clinical development of our product candidates or their submission for regulatory approval could be delayed, and our ability to deliver any products that we may develop on a timely basis could be impaired or precluded.

We are currently dependent on a single source of supply of the active ingredient in TELCYTA, Organichem Corporation. We recently entered into an agreement with a second source for supply of the active ingredient. While we are working to qualify this additional supplier, there is no certainty that this will occur. We are currently dependent upon two sources for the drug product manufacture of TELCYTA.

We presently depend upon a single source of supply for clinical quantities of the active ingredient in TELINTRA, Bachem Corporation. We recently entered into an agreement with a second source for supply of the active ingredient, and are working to qualify this additional supplier. We also depend upon a single source of supply for a key excipient used in the manufacture of TELINTRA, Lipoid GmbH. While we are evaluating potential alternative sources of these materials, we have no such alternative sources that are immediately available. Cardinal Health, Inc. is currently our sole drug product manufacturer of TELINTRA. While we have entered into an agreement with a second drug product manufacturer and are working to qualify this additional manufacturing source, there is no certainty this will occur.

If manufacturing is not performed in a timely manner, if our suppliers fail to perform or if our relationships with our suppliers or manufacturers should terminate, our clinical trials and commercialization of TELCYTA and TELINTRA could be delayed. We may not be able to enter into or maintain any necessary third-party manufacturing arrangements on acceptable terms, if at all. Our current dependence upon others for the manufacture of our product candidates and our anticipated dependence upon others for the manufacture of any products that we may develop may adversely affect our future profit margins and our ability to commercialize any products that we may develop on a timely and competitive basis.

**If we are unable to create sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions, we will not be able to commercialize any products that we may develop.**

We currently have no sales, marketing or distribution capabilities. In order to commercialize any products that we may develop, we must internally develop sales, marketing and distribution capabilities or establish collaborations or other arrangements with third parties to perform these services. We intend to market some products that we may develop directly in North America and rely on relationships with one or more pharmaceutical companies with established distribution systems and direct sales forces to market other products that we may develop and address other markets. We may not be able to establish in-house sales and distribution capabilities or relationships with third parties. To the extent that we enter into co-promotion or other licensing arrangements, any product revenues are likely to be lower than if we directly marketed and sold any products that we may develop, and any revenues we receive will depend upon the efforts of third parties, whose efforts may not be successful.

**Budget constraints may force us to delay our efforts to develop certain product candidates in favor of developing others, which may prevent us from commercializing all product candidates as quickly as possible.**

Because we have limited resources, and because research and development is an expensive process, we must regularly assess the most efficient allocation of our research and development budget. As a result, we may have to prioritize development candidates and may not be able to fully realize the value of some of our product candidates in a timely manner, as they will be delayed in reaching the market, if at all.



**If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates and any products that we may develop.**

The testing and marketing of medical products entail an inherent risk of product liability. Although we are not aware of any historical or anticipated product liability claims or specific causes for concern, if we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates and any products that we may develop. In addition, product liability claims may also result in withdrawal of clinical trial volunteers, injury to our reputation and decreased demand for any products that we may commercialize. We currently carry product liability insurance that covers our clinical trials up to a \$10 million annual aggregate limit. We will need to increase the amount of coverage if and when we have a product that is commercially available. If we are unable to obtain sufficient product liability insurance at an acceptable cost, potential product liability claims could prevent or inhibit the commercialization of any products that we may develop, alone or with corporate collaborators.

**If we use biological and hazardous materials in a manner that causes injury, we may be liable for damages.**

Our research and development activities involve the controlled use of potentially harmful biological materials, hazardous materials, chemicals and various radioactive compounds, and are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We cannot eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials. We currently have several coverages applying to various types of biological and pollution exposures for a total amount of \$350,000 in insurance, which we believe is a reasonably adequate amount to insulate us from damage claims arising from our use of hazardous materials. However, in the event of contamination or injury, we could be held liable for damages that result, and any liability could significantly exceed our coverage and resources.

**We have implemented anti-takeover provisions which could discourage or prevent a takeover, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.**

Provisions of our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would be beneficial to our stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- establishing a classified board of directors requiring that members of the board be elected in different years, which lengthens the time needed to elect a new majority of the board;
- authorizing the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares or change the balance of voting control and thwart a takeover attempt;
- prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;
- limiting the ability of stockholders to call special meetings of the stockholders;
- prohibiting stockholder action by written consent and requiring all stockholder actions to be taken at a meeting of our stockholders; and
- establishing 90 to 120 day advance notice requirements for nominations for election to the board of directors and for proposing matters that can be acted upon by stockholders at stockholder meetings.

**We adopted a stockholder rights plan that may discourage, delay or prevent a merger or acquisition that is beneficial to our stockholders.**

In November 2001, our board of directors adopted a stockholder rights plan that may have the effect of discouraging, delaying or preventing a merger or acquisition that is beneficial to our stockholders by diluting the ability of a potential acquiror to acquire us. Pursuant to the terms of our plan, when a person or group, except under certain circumstances, acquires 20% or more of our outstanding common stock or 10 business days after commencement or announcement of a tender or exchange offer for 20% or more of our outstanding common stock, the rights (except those rights held by the person or group who has acquired or announced an offer to acquire 20% or more of our outstanding common stock) would generally become exercisable for shares of our common stock at a discount. Because the potential acquiror's rights would not become exercisable for our shares of common stock at a discount, the potential acquiror would suffer substantial dilution and may lose its ability to acquire us. In addition, the existence of the plan itself may deter a potential acquiror from acquiring us. As a result, either by operation of the plan or by its potential deterrent effect, mergers and acquisitions of us that our stockholders may consider in their best interests may not occur.

**Substantial future sales of our common stock by us or by our existing stockholders could cause our stock price to fall.**

Additional equity financings or other share issuances by us, including shares issued in connection with strategic alliances, could adversely affect the market price of our common stock. Sales by existing stockholders of a large number of shares of our common stock in the public market or the perception that additional sales could occur could cause the market price of our common stock to drop. As of December 31, 2004, 43,832,529 shares of our common stock were outstanding, of which 43,560,274 shares were freely tradable and 272,255 shares were transferable in accordance with certain volume, notice and manner of sale restrictions under Rule 144.

**If we do not progress in our programs as anticipated, our stock price could decrease.**

For planning purposes, we estimate the timing of a variety of clinical, regulatory and other milestones, such as when a certain product candidate will enter clinical development, when a clinical trial will be completed or when an application for regulatory approval will be filed. Some of our estimates are included in this annual report. Our estimates are based on present facts and a variety of assumptions. Many of the underlying assumptions are outside of our control. If milestones are not achieved when we expect them to be, investors could be disappointed, and our stock price may decrease.

**Our stock price may be volatile, and you may not be able to resell your shares at or above your purchase price.**

Our stock prices and the market prices for securities of biotechnology companies in general have been highly volatile, with recent significant price and volume fluctuations, and may continue to be highly volatile in the future. During 2004, our common stock traded between \$29.67 and \$15.08. You may not be able to sell your shares quickly or at the market price if trading in our stock is not active or the volume is low. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock, some of which are beyond our control:

- developments regarding, or the results of, our clinical trials, including TELCYTA clinical trials;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations; publicity regarding actual or potential medical results relating to products under development by our competitors or us;
- regulatory developments in the United States and foreign countries;

- litigation;
- economic and other external factors or other disaster or crisis; or
- period-to-period fluctuations in our financial results.

**We will need to implement additional finance and accounting systems, procedures and controls to satisfy new reporting requirements.**

As a public reporting company, we are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the Securities and Exchange Commission, including expanded disclosures and accelerated reporting requirements and more complex accounting rules. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002 and other requirements will increase our costs and require additional management resources. We may need to continue to implement additional finance and accounting systems, procedures and controls to satisfy new reporting requirements. Compliance with Section 404 will first apply to this annual report. While we are able to complete a favorable assessment as to the adequacy of our internal control reporting for our fiscal year ending December 31, 2004, there is no assurance that we will be able to complete future favorable assessments as to the adequacy of our internal control reporting. If our independent registered public accounting firm is unable to provide us with future unqualified reports as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our internal controls over financial reporting, which could adversely affect our stock price.

**New and Potential New Accounting Pronouncements May Impact Our Future Financial Position and Results of Operations.**

There may be potential new accounting pronouncements or regulatory rulings, which may have an impact on our future financial position and results of operations. In particular, in December 2004, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards 123R (SFAS123R), "Share-Based Payment—An Amendment of FASB Statements No. 123 and 95, which eliminated the ability to account for share-based compensation transactions using Accounting Principles Board Opinion No. 25 (APB 25), "Accounting for Stock Issued to Employees." SFAS 123R will instead require companies to recognize compensation expense, using a fair-value based method, for costs related to share-based payments including stock options and employee stock purchase plans. SFAS 123R is effective for public companies in periods beginning after June 15, 2005. We will be required to implement the standard no later than the quarter that begins July 1, 2005. The cumulative effect of adoption, if any, applied on a modified prospective basis, would be measured and recognized on July 1, 2005. The adoption of FAS 123R and other potential changes will materially impact our results of operations.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

The following discussion about our market risk exposure involves forward-looking statements. We are exposed to market risk related mainly to changes in interest rates and we believe our exposure to market risk is immaterial. We do not use or hold derivative financial instruments.

Our investment policy is to manage our marketable securities portfolio to preserve principal and liquidity while maximizing the return on the investment portfolio. To minimize the exposure due to adverse shifts in interest rates we maintain investments of shorter maturities. Our marketable securities portfolio is primarily invested in corporate debt securities and commercial papers with an average maturity of under one year and a minimum investment grade rating of A or A-1 or better to minimize credit risk. Although changes in interest rates may affect the fair value of the marketable securities portfolio and cause unrealized gains or losses, such gains or losses would not be realized unless the investments were sold prior to maturity. Through our money managers, we maintain risk management control systems to monitor interest rate risk. The risk management control systems use analytical techniques, including sensitivity analysis. We have operated primarily in the United States and all funding activities with our collaborators to date have been made in U.S. dollars. Accordingly, we do not have any exposure to foreign currency rate fluctuations.

The table below presents the principal amounts and weighted-average interest rates by year of stated maturity for our investment portfolio:

	2005	2006	2007 and Beyond	Total	Fair Value at December 31, 2004
	(In thousands, except percentages)				
Available-for-sale securities . . . . .	\$105,964	\$1,744	\$22,350	\$130,058	\$129,840
Average interest rate . . . . .	2.29%	2.17%	2.58%	2.34%	

**Item 8. Financial Statements and Supplementary Data.**

All information required by this item is included on pages F-1 to F-18 in Item 15 of Part IV of this annual report on Form 10-K and is incorporated into this item by reference.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

Not applicable.

**Item 9A. Controls and Procedures.**

*Evaluation of Disclosure Controls and Procedures*

Based on their evaluation as of December 31, 2004, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were effective to ensure the information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

*Management's Report on Internal Control over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2004. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control-Integrated Framework. Our management has concluded that, as of December 31, 2004, our internal control over financial reporting was effective based on these criteria.

Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included elsewhere herein.

*Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2004 that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

*Inherent Limitations on Effectiveness of Controls*

Our management, including our chief executive officer and chief financial officer, does not expect that our procedures or our internal controls will prevent or detect all error and all fraud. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of our controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

## **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders  
Telik, Inc.

We have audited management's assessment, included in the accompanying Management's Report on Internal Controls over Financial Reporting, that Telik, Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Telik, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Telik, Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Telik, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Telik, Inc. as of December 31, 2004 and 2003, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2004 of Telik, Inc. and our report dated March 4, 2005 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
March 4, 2005

**Item 9B. Other Information.**

None.

## PART III

### Item 10. Directors and Executive Officers of the Registrant.

Information regarding directors and executive officers is incorporated by reference to the information set forth under the caption "Directors and Executive Officers" in our Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission by April 30, 2005.

We have adopted the Telik, Inc. Code of Conduct, a code of ethics with which every person who works for us is expected to comply. The Telik, Inc. Code of Conduct is filed as an exhibit to our annual report on Form 10-K filed on March 4, 2004 and is incorporated herein by reference. If we make any substantive amendments to the Telik, Inc. Code of Conduct or grant to any of our directors or executive officers any waiver including any implicit waiver, from a provision of the Telik, Inc. Code of Conduct, we will disclose the nature of the waiver or amendment in a Current Report on Form 8-K.

### Item 11. Executive Compensation.

Information regarding executive compensation is incorporated by reference to the information set forth under the caption "Executive Compensation" in our Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission by April 30, 2005.

### Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth under the caption "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in our Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission by April 30, 2005.

#### Equity Compensation Plan Information

The following table provides certain information with respect to all of the Company's equity compensation plans in effect as of December 31, 2004.

#### Equity Compensation Plan Information

Plan Category	(A) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(B) Weighted-average Exercise Price of Outstanding Options, Warrants and Rights	(C) Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A) (1))
Equity compensation plans approved by security holders .....	7,473,344	\$13.04	1,647,876 (2)
Equity compensation plans not approved by security holders .....	—	N/A	—
Total .....	<u>7,473,344</u>	<u>\$13.04</u>	<u>1,647,876 (2)</u>

- (1) Each year on January 1, since January 1, 2001, the aggregate number of shares of common stock that may be issued pursuant to stock awards under the 2000 Equity Incentive Plan is automatically increased by the lesser of 1,500,000 shares or 5% of the total number of shares of common stock outstanding on that date or such lesser amount as may be determined by our board of directors. In addition, the 2000 Employee Stock

Purchase Plan provides for the automatic increase on that date in the number of shares equal to the lesser of 150,000 shares or 1% of the outstanding shares on that date or such lesser amount as may be determined by the Board.

- (2) Includes 540,065 shares issuable under the 2000 Employee Stock Purchase Plan.

**Item 13. Certain Relationships and Related Transactions.**

Information regarding certain relationships and related transactions is incorporated by reference to the information set forth under the caption "Certain Transactions" in our Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission by April 30, 2005.

**Item 14. Principal Accountant Fees and Services.**

Information regarding principal accountant fees and services is incorporated by reference to the information set forth under the caption "Proposal 2—Ratification of Selection of Independent Auditors" in our Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission by April 30, 2005.

Consistent with Section 10A(i)(2) of the Securities Exchange Act of 1934, as added by Section 202 of the Sarbanes-Oxley Act of 2002, we are responsible for disclosing the non-audit services approved by our Audit Committee to be performed by Ernst & Young LLP, our external auditor. Non-audit services are defined as services other than those provided in connection with an audit or a review of our financial statements. In the period covered by this report, our Audit Committee pre-approved the following non-audit services rendered, currently being rendered, or to be rendered, to us by Ernst & Young LLP:

- all work required to be performed by Ernst & Young LLP in connection with preparing and giving consents required to be given in connection with our filings with the Securities and Exchange Commission; and
- services related to the Sarbanes-Oxley Act of 2002 for fiscal year ended December 31, 2004.



## PART IV

### Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this annual report:

1. *Financial Statements.* Our financial statements and the Report of Ernst & Young LLP, Independent Registered Public Accounting Firm, are included in Part IV of this Report on the pages indicated:

	<u>Page</u>
Report of Independent Registered Public Accounting Firm .....	F-1
Balance Sheets .....	F-2
Statements of Operations .....	F-3
Statement of Stockholders' Equity .....	F-4
Statements of Cash Flows .....	F-5
Notes to Financial Statements .....	F-6

2. *Financial Statement Schedules.* All schedules are omitted because they are not applicable or the required information is shown in the financial statements or the notes thereto.

3. *Exhibits:*

<u>Exhibit Number</u>	<u>Description</u>
3.1	Amended and Restated Certificate of Incorporation. (2)
3.2	Amended and Restated Bylaws. (1)
4.1	Specimen Common Stock Certificate. (1)
4.2	Amended and Restated Registration Rights Agreement, dated March 31, 2000, between Telik and holders of Telik's Series B, Series E, Series F, Series G, Series H, Series I, Series J and Series K preferred stock. (1)
4.3	Rights Agreement dated November 2, 2001, by and between Telik and Wells Fargo Bank Minnesota, N.A., replaced by EquiServe Trust Company, N.A. as Rights Agent. (6)
4.4	Registrant's Certificate of Designation of Series A Junior Participating Preferred Stock. (6)
10.1	Form of Indemnity Agreement. (1) (3)
10.2	2000 Equity Incentive Plan and related documents. (3) (4)
10.3	2000 Employee Stock Purchase Plan and Offering. (3) (4)
10.4	2000 Non-Employee Directors' Stock Option Plan and Agreement. (3) (4)
10.5	1996 Stock Option Plan and forms of grant thereunder. (3) (4)
10.6	1988 Stock Option Plan and forms of grant thereunder. (3) (4)
10.7	Form of Non-Plan Stock Option Agreement. (3) (4)
10.8*	Collaborative Research Agreement between Telik and Sankyo Company, Ltd., dated March 24, 1999, as amended. (1)
10.9*	Collaboration Agreement between Telik and Sanwa Kagaku Kenkyusho Co., Ltd., dated December 20, 1996, as amended. (1)
10.10*	License Agreement between Telik and Sanwa Kagaku Kenkyusho Co., Ltd., dated September 24, 1997, as amended. (1)

<u>Exhibit Number</u>	<u>Description</u>
10.11*	Screening Services Agreement between Telik and Sanwa Kagaku Kenkyusho Co., Ltd., dated December 20, 1996, as amended. (1)
10.12*	Third Amendment to Collaborative Agreement between Telik and Sanwa Kagaku Kenkyusho Co., Ltd., dated February 14, 2001. (5)
10.13*	Third Amendment to Screening Services Agreement between Telik and Sanwa Kagaku Kenkyusho Co., Ltd., dated February 14, 2001. (5)
10.14*	Second Amendment to License Agreement between Telik and Sanwa Kagaku Kenkyusho Co., Ltd., dated February 14, 2001. (5)
10.15*	License Agreement between Telik and the University of Arizona, dated January 8, 2001. (5)
10.16	Consulting Agreement for Individual Consultants between Gail L. Brown, M.D. and Telik, dated October 20, 1998, as amended. (1)
10.17	Employment Agreement between Cynthia M. Butitta and Telik, dated February 1, 2002. (3) (5)
10.18	Employment Agreement between Michael M. Wick, M.D., Ph.D. and Telik, dated December 10, 1997, as amended. (1) (3)
10.19*	Fourth Amendment to Screening Services Agreement between Telik and Sanwa Kagaku Kenkyusho Co., dated March 6, 2002. (7)
10.20	Lease between Telik and The Board of Trustees of the Leland Stanford Junior University, dated July 25, 2002. (8)
10.21	Master Lease Agreement between Telik and General Electric Capital Corporation, dated August 23, 2002, as amended. (8)
10.22	Master Security Agreement between Telik and General Electric Capital Corporation, dated August 23, 2002, as amended. (8)
10.23†	Manufacturing Supply Agreement dated July 1, 2004, by and between Telik and Organichem Corporation. (9)
14.1	Telik, Inc. Code of Conduct. (a)
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a).
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a).
32.1	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

\* Confidential treatment has been granted for portions of this document. The information omitted pursuant to such confidential treatment order has been filed separately with the Securities and Exchange Commission.

† Confidential treatment is pending for portions of this document. The information requested to be omitted pursuant to such confidential treatment order has been filed separately with the Securities and Exchange Commission.

- (1) Incorporated by reference to exhibits to our Registration Statement on Form S-1 filed on April 4, 2000, as amended (File No. 333-33868).
- (2) Incorporated by reference to exhibits to our Annual Report on Form 10-K for the year ended December 31, 2001 filed on March 27, 2002.
- (3) Management contract or compensatory arrangement.
- (4) Incorporated by reference to exhibits to our Registration Statement on Form S-8 filed on August 30, 2000 (File No. 333-44826).

- (5) Incorporated by reference to exhibits to our Annual Report on Form 10-K for the year ended December 31, 2000 initially filed on March 28, 2001 as amended on Form 10-K/A filed on September 20, 2001.
- (6) Incorporated by reference to exhibits to our Current Report on Form 8-K dated November 2, 2001 filed on November 5, 2002.
- (7) Incorporated by reference to exhibits to our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2002 filed on May 7, 2002.
- (8) Incorporated by reference to exhibits to our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2002 filed on November 13, 2002.
- (9) Incorporated by reference to exhibits to our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2004 filed on November 8, 2004.
- (a) Incorporated by reference to exhibits to our Annual Report on Form 10-K for the year ended December 31, 2003 filed on March 4, 2004.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

TELIK, INC.

/s/ CYNTHIA M. BUTITTA

Cynthia M. Butitta  
Chief Operating and Chief Financial Officer  
(Principal Financial and Accounting Officer)

Dated: March 9, 2005

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Michael M. Wick, M.D., Ph.D. and Cynthia M Butitta, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments to this Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ MICHAEL M. WICK</u> Michael M. Wick, M.D., Ph.D.	Chief Executive Officer and Director (Principal Executive Officer)	March 9, 2005
<u>/s/ CYNTHIA M. BUTITTA</u> Cynthia M. Butitta	Chief Operating Officer and Chief Financial Officer (Principal Financial and Accounting Officer)	March 9, 2005
<u>/s/ EDWARD W. CANTRALL</u> Edward W. Cantrall, Ph.D.	Director	March 9, 2005
<u>/s/ MARY ANN GRAY</u> Mary Ann Gray, Ph.D.	Director	March 9, 2005
<u>/s/ ROBERT W. FRICK</u> Robert W. Frick	Director	March 9, 2005
<u>/s/ STEVEN R. GOLDRING</u> Steven R. Goldring, M.D.	Director	March 9, 2005

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ RICHARD B. NEWMAN</u> Richard B. Newman	Director	March 9, 2005
<u>/s/ STEFAN RYSER</u> Stefan Ryser, Ph.D.	Director	March 9, 2005
<u>/s/ HERWIG VON MORZE</u> Herwig von Morze, Ph.D.	Director	March 9, 2005

## **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders  
Telik, Inc.

We have audited the accompanying balance sheets of Telik, Inc. as of December 31, 2004 and 2003, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Telik, Inc. at December 31, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with the U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Telik Inc.'s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 4, 2005 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
March 4, 2005

**TELIK, INC.**  
**BALANCE SHEETS**  
(In thousands, except share and per share data)

		December 31,	
		2004	2003
<b>Assets</b>			
Current assets:			
Cash and cash equivalents	\$ 56,221	\$ 76,851	
Short-term investments	80,630	122,441	
Other receivables	517	354	
Prepays and other current assets	1,640	1,417	
Total current assets	139,008	201,063	
Property and equipment, net	5,269	5,388	
Restricted investments	1,796	1,796	
Other assets	60	60	
Total assets	\$ 146,133	\$ 208,307	
<b>Liabilities and Stockholders' Equity</b>			
Current liabilities:			
Accounts payable	\$ 4,697	\$ 2,623	
Accrued clinical trial costs	7,719	4,174	
Accrued compensation	3,349	3,232	
Accrued liabilities	529	836	
Deferred revenue	19	25	
Current portion of capital leases and loans	1,339	907	
Total current liabilities	17,652	11,797	
Non-current portion of capital leases and loans	1,029	1,493	
Other liabilities	1,108	715	
Commitments			
Stockholders' equity:			
Preferred stock, \$0.01 par value: 5,000,000 shares authorized; none issued or outstanding	—	—	
Common stock, \$0.01 par value: 100,000,000 shares authorized; shares issued and outstanding: 43,832,529 in 2004 and 43,583,457 in 2003	438	436	
Additional paid-in capital	363,872	361,840	
Deferred stock compensation, net	—	(93)	
Accumulated other comprehensive income (loss)	(218)	50	
Accumulated deficit	(237,748)	(167,931)	
Total stockholders' equity	126,344	194,302	
Total liabilities and stockholders' equity	\$ 146,133	\$ 208,307	

See accompanying Notes to Financial Statements.

**TELIK, INC.**

**STATEMENTS OF OPERATIONS**  
(In thousands, except per share amounts)

	Years Ended December 31,		
	2004	2003	2002
Contract revenue from collaborations .....	\$ 163	\$ 436	\$ 1,245
Other revenue .....	—	—	42
Total revenues .....	163	436	1,287
Operating costs and expenses:			
Research and development .....	61,868	42,311	30,549
General and administrative .....	10,613	9,915	6,665
Total operating costs and expenses .....	72,481	52,226	37,214
Loss from operations .....	(72,318)	(51,790)	(35,927)
Interest income .....	2,702	1,303	1,161
Interest expense .....	(201)	(155)	(16)
Net loss .....	<u>\$(69,817)</u>	<u>\$(50,642)</u>	<u>\$(34,782)</u>
Basic and diluted net loss per common share .....	<u>\$ (1.60)</u>	<u>\$ (1.38)</u>	<u>\$ (1.17)</u>
Shares used to calculate basic and diluted net loss per common share .....	<u>43,701</u>	<u>36,812</u>	<u>29,786</u>

See accompanying Notes to Financial Statements.



TELIK, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY  
(In thousands)

	Common Stock Shares	Common Stock	Additional Paid-in Capital	Deferred Stock Compensation	Notes Receivable	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
<b>Balances at December 31, 2001</b>	27,765	\$278	\$134,812	\$(1,173)	\$(105)	\$ 33	\$ (82,507)	\$ 51,338
Comprehensive loss:								
Net loss	—	—	—	—	—	—	(34,782)	(34,782)
Change in unrealized gain on available for sale investments	—	—	—	—	—	(3)	—	(3)
Comprehensive loss	—	—	—	—	—	—	—	(34,785)
Issuance of common stock in follow-on public offering, net of issuance costs of \$0.5 million	7,475	75	80,214	—	—	—	—	80,289
Common stock issued under stock option and purchase plans	327	3	1,573	—	—	—	—	1,576
Stock options issued to non-employees	—	—	171	—	—	—	—	171
Payment on promissory note	—	—	—	—	105	—	—	105
Deferred stock compensation amortization, net of reversal for terminated employees	—	—	(55)	566	—	—	—	511
<b>Balances at December 31, 2002</b>	35,567	356	216,715	(607)	—	30	(117,289)	99,205
Comprehensive loss:								
Net loss	—	—	—	—	—	—	(50,642)	(50,642)
Change in unrealized gain on available for sale investments	—	—	—	—	—	20	—	20
Comprehensive loss	—	—	—	—	—	—	—	(50,622)
Issuance of common stock in follow-on public offering, net of issuance costs of \$ 0.5 million	7,625	76	142,740	—	—	—	—	142,816
Common stock issued under stock option and purchase plans	391	4	2,214	—	—	—	—	2,218
Stock options issued to non-employees	—	—	266	—	—	—	—	266
Deferred stock compensation amortization, net of reversal for terminated employees	—	—	(95)	514	—	—	—	419
<b>Balances at December 31, 2003</b>	43,583	436	361,840	(93)	—	50	(167,931)	194,302
Comprehensive loss:								
Net loss	—	—	—	—	—	—	(69,817)	(69,817)
Change in unrealized gain on available for sale investments	—	—	—	—	—	(268)	—	(268)
Comprehensive loss	—	—	—	—	—	—	—	(70,085)
Common stock issued under stock option and purchase plans	250	2	1,835	—	—	—	—	1,837
Stock options issued to non-employees	—	—	197	—	—	—	—	197
Deferred stock compensation amortization	—	—	—	93	—	—	—	93
<b>Balances at December 31, 2004</b>	43,833	\$438	\$363,872	\$ —	\$ —	\$(218)	\$(237,748)	\$126,344

See accompanying Notes to Financial Statements.

**TELIK, INC.**  
**STATEMENTS OF CASH FLOWS**  
(In thousands)

	Years Ended December 31,		
	2004	2003	2002
<b>Cash flows from operating activities:</b>			
Net loss	\$ (69,817)	\$ (50,642)	\$ (34,782)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,370	1,108	614
Amortization of deferred stock compensation	93	419	511
Stock options granted to non-employees	197	266	171
Forgiveness of notes receivable from related parties	—	29	28
Changes in assets and liabilities:			
Other receivables	(163)	1,551	(1,782)
Prepays and other current assets	(223)	(420)	(129)
Other assets	—	21	(74)
Accounts payable	2,074	(3,599)	2,884
Accrued liabilities	3,748	6,243	747
Deferred revenue	(6)	(386)	(245)
Net cash used in operating activities	(62,727)	(45,410)	(32,057)
<b>Cash flows from investing activities:</b>			
Purchases of investments	(134,357)	(164,498)	(172,458)
Sales of investments	141,685	86,230	1,900
Maturities of investments	34,215	21,645	120,423
Transfer from (to) restricted investments	—	2,000	(3,796)
Purchases of property and equipment	(1,251)	(3,978)	(1,064)
Net cash provided by (used in) investing activities	40,292	(58,601)	(54,995)
<b>Cash flows from financing activities:</b>			
Proceeds from capital loans	1,091	1,688	303
Principal payments under capital leases and loans	(1,123)	(548)	(41)
Net proceeds from issuance of common stock	1,837	145,034	81,865
Payment of promissory note from employee	—	—	105
Net cash provided by financing activities	1,805	146,174	82,232
Net change in cash and cash equivalents	(20,630)	42,163	(4,820)
Cash and cash equivalents at beginning of period	76,851	34,688	39,508
Cash and cash equivalents at end of period	\$ 56,221	\$ 76,851	\$ 34,688
<b>Supplemental information:</b>			
Interest paid	\$ 201	\$ 155	\$ 16
<b>Non-cash financing activities:</b>			
Equipment acquired under capital leases	\$ —	\$ 839	\$ 143

See accompanying Notes to Financial Statements.

## **TELIK, INC.**

### **NOTES TO FINANCIAL STATEMENTS**

#### **1. Summary of Significant Accounting Policies**

##### **Nature of Operations and Basis of Presentation**

Telik, Inc. ("Telik," "We" or, the "Company") was incorporated in the state of Delaware in October 1988 as Terrapin Diagnostics, Inc. which changed its name in June 1989 to Terrapin Technologies, Inc. and again in May 1998 to Telik, Inc. We are engaged in the discovery and development of small molecule therapeutics. We operate in only one segment.

We have incurred net losses since inception and we expect to incur substantial and increasing losses for at least the next few years as we expand research and development activities. To date, we have funded operations primarily through the sale of equity securities, non-equity payments from collaborators and interest income. Future revenue, if any, for at least the next few years is expected to consist primarily of payments under corporate collaborations and interest income. The process of developing products will require significant additional research and development, preclinical testing and clinical trials, as well as regulatory approval. We expect these activities, together with general and administrative expenses, to result in substantial operating losses for the foreseeable future. We will not receive product revenue unless we, or our collaborative partners complete clinical trials, obtain regulatory approval and successfully commercialize one or more of our products.

We expect continuing losses over the next several years. We plan to obtain capital through public or private equity or debt financing, capital lease financing and collaborative arrangements with corporate partners. We may have to seek other sources of capital or reevaluate our operating plans if we are unable to consummate some or all of the capital financing arrangements noted above.

##### **Use of Estimates**

In preparing our financial statements to conform with U.S. generally accepted accounting principles, we make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Actual results may differ from these estimates.

##### **Cash and Cash Equivalents and Short-Term Investments**

We invest our excess cash in money market funds and in highly liquid debt instruments of the U.S. government, its agencies and municipalities and corporate notes. All highly liquid investments with stated maturities of three months or less from date of purchase are classified as cash equivalents; highly liquid investments with stated maturities of greater than three months are classified as short-term investments.

We determine the appropriate classification of our investments in debt securities at the time of purchase and reevaluate such designation at each balance sheet date. We have classified our cash equivalents and investments as available-for-sale securities as we do not intend to hold securities with stated maturities greater than twelve months until maturity. In response to changes in the availability of and the yield on alternative investments as well as liquidity requirements, we occasionally sell these securities prior to their stated maturities. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported as a component of accumulated other comprehensive income (loss). Any realized gains or losses on the sale of short-term investments are determined on a specific identification method, and such gains and losses are reflected as a component of interest income or expense.

##### **Restricted Investments**

Under certain operating lease agreements, we may be required from time to time to set aside cash as collateral. At December 31, 2004 and 2003, we had approximately \$1.8 million of restricted investments related to such agreements.

### **Fair Value of Financial Instruments**

The fair value of our cash equivalents and investments is based on quoted market prices. The fair value of capital lease obligations and loans is based on current interest rates available to us for debt instruments with similar terms, degrees of risk, and remaining maturities. The carrying amount of cash equivalents, investments and capital lease and loan obligations are considered to be representative of their respective fair value at December 31, 2004 and 2003.

### **Property and Equipment**

Property and equipment are stated at cost. We calculate depreciation using the straight-line method over the estimated useful lives of the assets, which range from three to seven years. We amortize furniture and equipment leased under capital leases and leasehold improvements using the straight-line method over the estimated useful lives of the respective assets or the lease term, whichever is shorter. Amortization of assets under capital leases is included in depreciation expense.

### **Impairment of Long-lived Assets**

We regularly evaluate our long-lived assets for indicators of possible impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is assessed using discounted cash flows.

### **Revenue Recognition**

Our revenues have been generated from license and research agreements with collaborators. We recognize cost reimbursement revenue under these collaborative agreements as the related research and development costs are incurred. We recognize milestone fees upon completion of specified milestones according to contract terms. Deferred revenue represents the portion of research payments received that has not been earned.

We also have royalty and licensing agreements with other pharmaceutical, biotechnology and genomics companies. Under these agreements, we may receive fees for collaborative research efforts, royalties on future sales of products, or some combination of these items. We recognize nonrefundable signing or license fees that are not dependent on future performance under these agreements as revenue when received or over the term of the arrangement if we have continuing performance obligations.

We have received United States government grants, which support research efforts in defined projects. We recognize revenue from such grants as costs relating to the grants are incurred.

### **Research and Development**

Our research and development expenses include salaries and benefits costs, fees for contractors, consultants and third party contract research organizations, and an allocation of facility and administrative costs. Research and development expenses consist of costs incurred for drug and product development, manufacturing, clinical activities, discovery research, screening and identification of product candidates, and preclinical studies. All such costs are charged to research and development expenses as incurred.

Clinical development costs are a significant component of research and development expenses. We have a history of contracting with third parties that perform various clinical trial activities on our behalf in the on-going development of our product candidates. The financial terms of these contracts are subject to negotiations and may vary from contract to contract and may result in uneven payment flows. We accrue and expense costs for clinical trial activities performed by third parties based upon estimates of the percentage of work completed over

the life of the individual study in accordance to agreements established with contract research organizations and clinical trial sites. We determine our estimates through discussion with internal clinical personnel and outside service providers as to progress or stage of completion of trials or services and the agreed upon fee to be paid for such services. These estimates may or may not match the actual services performed by the organizations as determined by patient enrollment levels and related activities. We monitor patient enrollment levels and related activities to the extent possible; however, if we underestimated activity levels associated with various studies at a given point in time, we could record significant research and development expenses in future periods.

### Stock-based Compensation

We issue stock options to our employees and outside directors and provide employees the right to purchase our stock pursuant to stockholder approved stock option and employee stock purchase programs. We account for our stock-based compensation plans under the intrinsic value method of accounting as defined by Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. For pro forma disclosures, the estimated fair value of the options is amortized over the vesting period, typically four years, and the estimated fair value of the stock purchases is amortized over the six-month purchase period. The following table illustrates the effect on net loss and net loss per common share if we had accounted for our stock option and stock purchase plans under the fair value method of accounting under Statement of Financial Accounting Standards, or SFAS, No. 123, "Accounting for Stock Based Compensation," as amended by SFAS No. 148:

	Years Ended December 31,		
	2004	2003	2002
	(in thousands)		
Net loss—as reported	\$(69,817)	\$(50,642)	\$(34,782)
Add: Stock-based employee compensation expense included in reported net loss	93	419	511
Deduct: Total stock-based employee compensation expense under the fair value based method for all awards	(15,028)	(8,774)	(6,863)
Net loss—pro forma	<u>\$(84,752)</u>	<u>\$(58,997)</u>	<u>\$(41,134)</u>
Basic and diluted net loss per common share—as reported	<u>\$ (1.60)</u>	<u>\$ (1.38)</u>	<u>\$ (1.17)</u>
Basic and diluted net loss per common share—pro forma	<u>\$ (1.94)</u>	<u>\$ (1.60)</u>	<u>\$ (1.38)</u>

We estimate the fair value of our options using the Black-Scholes option value model, which is one of several methods that can be used to estimate option values. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. Option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. Our options have characteristics significantly different from those of traded options, and changes in the subjective input assumptions can materially affect the fair value estimates. The fair value of options granted and employee purchase plan shares were estimated at the date of grant using a Black-Scholes pricing model with the following weighted-average assumptions:

	Stock Option Plans			Stock Purchase Plan		
	2004	2003	2002	2004	2003	2002
Expected stock price volatility	70.4%	77.1%	81.5%	78.9%	86.8%	106.4%
Risk-free interest rate	3.29%	2.99%	3.54%	1.34%	2.09%	4.06%
Expected life (in years)	5.08	5.03	5.00	1.33	1.36	1.38
Expected dividend yield	—	—	—	—	—	—

Stock compensation expense for options granted to non-employees has been determined in accordance with SFAS 123 and EITF 96-18, "Accounting for Equity Investments that are issued to other than Employees for

Acquiring, or in Conjunction with Selling Goods or Services,” as the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of options granted to non-employees is periodically re-measured as the underlying options vest.

In December 2004, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards 123R (SFAS123R), “Share-Based Payment—An Amendment of FASB Statements No. 123 and 95, which eliminated the ability to account for share-based compensation transactions using Accounting Principles Board Opinion No. 25 (APB 25), “Accounting for Stock Issued to Employees.” SFAS 123R will instead require companies to recognize compensation expense, using a fair-value based method, for costs related to share-based payments including stock options and employee stock purchase plans. SFAS 123R is effective for public companies in periods beginning after June 15, 2005. We will be required to implement the standard no later than the quarter that begins July 1, 2005. The cumulative effect of adoption, if any, applied on a modified prospective basis, would be measured and recognized on July 1, 2005. Current estimates of option values using the Black Scholes method (as shown above) may not be indicative of results from valuation methodologies ultimately adopted. The adoption of SFAS 123R will have a material impact on our results of operations.

### Comprehensive Income (loss)

Components of other comprehensive income (loss), including unrealized gains and losses on available-for-sale investments, were included as part of total comprehensive income (loss). For all periods presented, we have disclosed comprehensive income (loss) in the statements of stockholders’ equity.

### Net Loss per Common Share

Basic earnings per share excludes any dilutive effects of options and shares subject to repurchase. Diluted earnings per share includes the impact of potentially dilutive securities.

	Years Ended December 31,		
	2004	2003	2002
	(In thousands, except per share amounts)		
Net loss .....	\$(69,817)	\$(50,642)	\$(34,782)
Weighted average shares of common stock outstanding .....	43,701	36,812	29,823
Less: weighted average outstanding shares subject to repurchase ....	—	—	(37)
Weighted average shares used in computing basic and diluted net loss per share .....	43,701	36,812	29,786
Basic and diluted net loss per share .....	<u>\$ (1.60)</u>	<u>\$ (1.38)</u>	<u>\$ (1.17)</u>

The following table reflects options outstanding that could potentially dilute basic earnings per share in the future, but were excluded from the computation of diluted net loss per share, as their effect would have been antidilutive.

	December 31,		
	2004	2003	2002
Outstanding options .....	<u>7,473,344</u>	<u>5,297,010</u>	<u>4,850,665</u>

### Reclassification

Certain prior period amounts reflect the reclassification of long-term investments to short-term investments to conform to the current period presentation as we do not intend to hold securities with stated maturities greater than twelve months to maturity.

## Recent Accounting Pronouncements

In March 2004, the FASB approved Emerging Issues Task Force (EITF) Issue No. 03-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments." The objective of this issue is to provide guidance for identifying other-than-temporarily impaired investments. EITF No. 03-1 also provides new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB issued EITF No. 03-1-1, which delayed the effective date of EITF No. 03-1, with the exception of certain disclosure requirements. We do not believe that the adoption of EITF No. 03-1 will have a material impact on our financial condition and results of operations.

## 2. Cash and Cash Equivalents, Investments and Restricted Investments

The following is a summary of cash and cash equivalents, investments and restricted investments. Long-term investments for 2003 have been reclassified to short-term investments to conform with our presentation in 2004. We do not intend to hold securities with stated maturities greater than twelve months to maturity.

	December 31, 2004			
	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Certificate of deposits .....	\$ 1,796	\$ —	\$ —	\$ 1,796
Corporate notes .....	29,146	—	(32)	29,114
Commercial paper .....	47,213	—	(1)	47,212
Government notes .....	53,699	6	(191)	53,514
Cash and money market funds .....	7,011	—	—	7,011
Total .....	<u>\$138,865</u>	<u>\$ 6</u>	<u>\$(224)</u>	<u>\$138,647</u>

Reported as:

Cash and cash equivalents .....	\$ 56,221
Short term investments .....	80,630
Restricted investments .....	1,796
Total .....	<u>\$138,647</u>

	December 31, 2003			
	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Certificate of deposits .....	\$ 1,796	\$ —	\$ —	\$ 1,796
Corporate notes .....	80,860	26	(7)	80,879
Commercial paper .....	99,413	9	—	99,422
Government notes .....	10,606	33	(11)	10,628
Cash and money market funds .....	8,363	—	—	8,363
Total .....	<u>\$201,038</u>	<u>\$ 68</u>	<u>\$(18)</u>	<u>\$201,088</u>

Reported as:

Cash and cash equivalents .....	\$ 76,851
Short term investments .....	122,441
Restricted investments .....	1,796
Total .....	<u>\$201,088</u>

The net realized gains on sales of available-for-sales investments were not material in 2004 and 2003. Realized gains and losses were calculated based on the specific identification method.

The following is a summary of the cost and estimated fair value of available-for-sale securities at December 31, 2004 and 2003, classified by stated maturity date of the security:

	2004		2003	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
	(in thousands)			
Mature in less than one year .....	\$105,964	\$105,762	\$139,069	\$139,113
Mature in one to three years .....	1,744	1,728	6,460	6,466
Mature in over three years .....	22,350	22,350	45,350	45,350
Total .....	<u>\$130,058</u>	<u>\$129,840</u>	<u>\$190,879</u>	<u>\$190,929</u>

### 3. Property and Equipment

Property and equipment consist of the following:

	December 31,	
	2004	2003
	(in thousands)	
Laboratory equipment .....	\$ 6,476	\$ 5,450
Office furniture and equipment .....	337	178
Leasehold improvements .....	3,196	3,196
	10,009	8,824
Less accumulated depreciation and amortization .....	(4,740)	(3,436)
Property and equipment, net .....	<u>\$ 5,269</u>	<u>\$ 5,388</u>

Property and equipment includes assets under capitalized leases at December 31, 2004 and 2003 of approximately \$ 1.0 million. Accumulated amortization related to leased assets was approximately \$ 614,000 and \$ 254,000 at December 31, 2004 and 2003.

### 4. Restricted Investments

As of December 31, 2004, \$1.8 million of our total cash and cash equivalents was restricted, held in a certificate of deposit for specific purposes. Under our operating lease agreement for the facility located in Palo Alto, California, we are required to maintain a security deposit in the form of a letter of credit equal to approximately \$1.8 million (see Note 5).

### 5. Commitments

#### Capital Leases and Loans

At December 31, 2004, there were no draws available under our Master Lease and Master Security credit facilities of approximately \$2.5 million. The lease and credit facilities, secured by equipment and tenant improvements and bearing interest rates between 4.3% and 11.5%, were fully utilized by the end of 2003. Pursuant to the terms of these credit facilities, we are required to maintain a balance of cash and investments of at least \$20.5 million. In the event our cash and investments balance falls below \$20.5 million, we are obligated to provide the lessor with a continuing irrevocable letter of credit from a financial institution acceptable to the lessor in an amount equal to 100% of the outstanding balance of all indebtedness and loans. At December 31, 2004, we were in compliance with the financial covenants.

At December 31, 2004, draws under our Loan and Security Agreement credit facility totaled approximately \$1.5 million, bearing interest rates between 5.91% and 6.98%. The credit facility was fully utilized as of



July 2004. Pursuant to the terms of the credit facility, we are required to maintain a balance of cash and investments with the lender of at least \$5.0 million. At December 31, 2004, we were in compliance with this financial requirement.

As of December 31, 2004, payments under capital leases and loan are as follows:

	<u>Capital Leases</u>	<u>Loans</u>	<u>Total</u>
	(in thousands)		
Year ending December 31:			
2005 .....	\$318	\$1,151	\$1,469
2006 .....	246	673	919
2007 .....	—	148	148
Total .....	\$564	\$1,972	2,536
Less amount representing interest .....			168
Present value of future payments .....			2,368
Reported as current portion .....			1,339
Non-current portion .....			<u>\$1,029</u>

### Operating Leases

In July 2002, we entered into a lease for a new research and office facility of approximately 92,000 square feet located at 3165 Porter Drive in Palo Alto, California. The term of the lease is approximately 11.5 years, commencing in January 2003 and terminating in May 2014. We have the option to extend the lease term for an additional term of five years. Under the terms of this lease, the lessor agreed to finance up to \$5.0 million in leasehold improvements to be made to the facility. Our financial commitment for the full term of the Palo Alto lease is approximately \$39.1 million, which includes repayment, over a period of 10 years, of \$3.0 million of the total \$5.0 million in leasehold improvements financed by the lessor. The remaining \$2.0 million in leasehold improvements financed by the lessor will be payable, subject to certain extension provisions, in a balloon payment at the commencement of the third year of the lease. Prior to this balloon payment, interest only payments are payable monthly on the outstanding balance of the remaining \$2.0 million in leasehold improvements financed by the lessor. In January 2005, we renegotiated the payment term for the remaining \$2 million balloon payment. The lessor agreed to amortize the amount owed at an interest rate of 6% over twelve months with equal monthly payments of principal and interest of approximately \$172,000 through December 31, 2005. All amounts owed related to the remaining \$2.0 million have been included in the total rental payments reflected in the table below. Pursuant to the terms of the lease, we are required to maintain a security deposit, in the form of a letter of credit equal to approximately \$1.8 million. This letter of credit must be secured by either a deposit account or a securities account and at December 31, 2004, the security deposit is in the form of securities that are classified in the balance sheet as restricted investments. This collateral account is managed in accordance with our investment policy, and is restricted as to withdrawal.

We also have office equipment leases of approximately \$75,000 with terms ranging from 36 months to 60 months.

Future minimum rental payments under the operating leases as of December 31, 2004 are as follows:

	<u>Operating Leases</u> (in thousands)
Year ending December 31,	
2005 .....	5,268
2006 .....	3,296
2007 .....	3,391
2008 .....	3,483
2009 .....	3,588
Thereafter .....	16,506
Total .....	<u>\$35,532</u>

Rent expense under operating leases was approximately \$3.3 million in 2004, \$4.1 million in 2003 and \$581,000 in 2002.

## 6. Stockholders' Equity

### Follow-on Public Offerings

In November 2003, we completed a follow-on offering in which we sold 6.5 million shares and a corporate stockholder sold 1 million shares of our common stock at a price of \$20.00 per share. In December 2003, the underwriters fully exercised their option to purchase 1.125 million shares of our common stock at \$20.00 per share from us to cover over-allotments. We received proceeds of approximately \$142.8 million from the offerings, net of underwriting discounts and commissions and related expenses.

In October 2002, we completed a follow-on offering of 7.5 million shares of our common stock, at \$11.50 per share, pursuant to this registration statement. We received proceeds of approximately \$80.3 million from this offering, net of underwriting discounts and commissions and related expenses.

### Stockholder Rights Plan

In October 2001, our Board of Directors approved the adoption of a Stockholder Rights Plan, which provided for the distribution of one preferred share purchase right (a "Right") for each outstanding share of common stock of the Company. The dividend was paid on November 14, 2001 to the stockholders of record on that date. Each Right entitles the registered holder to purchase from the Company one one-hundredth of a share of Series A Junior Participating Preferred Stock, par value \$0.01 per share (the "Preferred Shares"), at a price of \$90.00 per one one-hundredth of a Preferred Share (the "Purchase Price"), subject to adjustment. The Rights will be exercisable the earlier of (i) the date of a public announcement that a person, entity or group of affiliated or associated persons have acquired beneficial ownership of 20% or more of the outstanding common shares (an "Acquiring Person"), or (ii) ten business days (or such later date as may be determined by action of the Board of Directors prior to such time as any person or entity becomes an Acquiring Person) following the commencement of, or announcement of an intention to commence, a tender offer or exchange offer the consummation of which would result in any person or entity becoming an Acquiring Person.

In the event that any person, entity or group of affiliated or associated persons become an Acquiring Person, each holder of a Right will have the right to receive, upon exercise, the number of common shares having a market value of two times the exercise price of the Right. In the event that the Company is acquired in a merger or other business combination transaction or 50% or more of its consolidated assets or earning power are sold to an Acquiring Person, its associates or affiliates or certain other persons in which such persons have an interest, each holder of a Right will have the right to receive, upon the exercise at the then-current exercise price of the Right, that number of shares of common stock of the acquiring company which at the time of such transaction will have a market value of two times the exercise price of the Right. At any time after an Acquiring Person

becomes an Acquiring Person and prior to the acquisition by such Acquiring Person of 50% or more of the outstanding common shares, the Board of Directors of the Company may exchange the Rights (other than Rights owned by such person or group which have become void), in whole or in part, at an exchange ratio of one common share, or one one-hundredth of a Preferred Share, per Right (or, at the election of the Company, the Company may issue cash, debt, stock or a combination thereof in exchange for the Rights), subject to adjustment. The Rights will expire on November 14, 2011, unless redeemed or exchanged by the Company.

### **2000 Equity Incentive Plan**

In March 2000, we adopted the 2000 Equity Incentive Plan (the "2000 Plan") and reserved 2,000,000 shares of Telik common stock for issuance under the 2000 Plan. In addition the 2000 Plan provides for annual increases in the number of shares available for issuance under the 2000 Plan beginning January 1, 2001. The number of additional shares to be reserved automatically will be equal to the lesser of 1,500,000 shares, 5% of the outstanding shares on the date of the annual increase or such amount as may be determined by the Board of Directors. Options granted under the 2000 Plan may be either incentive stock options ("ISOs") or nonstatutory stock options ("NSOs"). For ISOs and NSOs, the option price shall be at least 100% and 85%, respectively, of the closing price of our common stock on the date of the grant, or in the event there is no public market for the common stock, of the fair value on the date of the grant, as determined by the board of directors. If, at any time we grant an option, and the optionee directly or by attribution owns stock possessing more than 10% of the total combined voting power of all classes of stock of Telik, the option price shall be at least 110% of the fair value and shall not be exercisable more than five years after the date of grant. Options generally vest over a period of four years from the date of grant. Options granted under the 2000 Plan expire no later than 10 years from the date of grant.

At December 31, 2004, 2003 and 2002 authorized and unissued shares of common stock for issuance under the 2000 Plan were 7,130,031, 5,736,094 and 4,426,410. At December 31, 2004, 2003 and 2002, 6,078,679, 3,900,947 and 3,380,002 options were outstanding under the 2000 Plan.

### **2000 Non-Employee Directors' Stock Option Plan**

In March 2000, we adopted the 2000 Non-Employee Directors' Stock Option Plan (the "Directors' Plan") and reserved a total of 300,000 shares of common stock for issuance thereunder. Each non-employee director at the initial public offering date was granted a NSO to purchase 20,000 shares of common stock, and each non-employee director who subsequently becomes a director of Telik will be automatically granted a NSO to purchase 20,000 shares of common stock on the date on which such person first becomes a director. Upon the day immediately following each annual stockholder meeting each non-employee director will automatically be granted a NSO to purchase 5,000 shares of common stock or an option to purchase an amount of shares prorated for the part of the year served as non-employee director. The exercise price of options under the Directors' Plan will be equal to the fair market value of the common stock on the date of grant. The maximum term of the options granted under the Directors' Plan is ten years. All grants under the Directors' Plan will vest over a period of four years from date of grant, one fourth vesting one year after the date of the grant and thereafter the balance vesting monthly. The Directors' Plan will terminate in March 2010 unless terminated earlier in accordance with the provisions of the Directors' Plan. At December 31, 2004, 2003 and 2002 authorized and unissued shares of common stock for issuance under the Directors' Plan were 251,459 for all periods. At December 31, 2004, 2003 and 2002, options outstanding under the Directors' Plan were 195,000, 145,000 and 70,000.

### **2000 Employee Stock Purchase Plan**

In March 2000, we adopted the 2000 Employee Stock Purchase Plan (the "Purchase Plan"). We reserved a total of 250,000 shares of our common stock for issuance under the Purchase Plan. In addition, the Purchase Plan provides for annual increases in the number of shares available for issuance under the Purchase Plan beginning January 1, 2001. The number of additional shares to be reserved automatically will be equal to the lesser of 150,000 shares, 1% of the outstanding shares on the date of the annual increase or such amount as may be

determined by the Board of Directors. The Purchase Plan permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. The price at which the stock is purchased is equal to the lower of 85% of the fair market value of the common stock on the first day of the offering or 85% of the fair market value of our common stock on the purchase date. The initial offering period commenced on the effective date of the initial public offering, August 11, 2000. Through the end of December 31, 2004, we have issued a total of 309,935 shares under this plan, and 540,065 shares remain available for future issuance. The weighted average per share fair value for shares purchased under our Purchase Plan during 2004, 2003 and 2002 was \$6.36, \$5.33 and \$3.72.

### 1996 Stock Option Plan

The 1996 Stock Option Plan (the "1996 Plan") was adopted in April 1996. The terms are similar to the 2000 Plan. At December 31, 2004, 2003 and 2002, 1,199,665, 1,212,085 and 1,311,152 options were outstanding under the 1996 Plan. The 1996 Plan was terminated upon our initial public offering and no new options can be granted under this plan. The termination of the 1996 Plan had no effect upon outstanding options under the plan.

### 1988 Stock Option Plan

The 1988 Stock Option Plan (the "1988 Plan") was adopted in February 1989. At December 31, 2004, no options were outstanding. At December 31, 2003 and 2002, 38,998 and 89,511 options were outstanding under the 1988 Plan. The 1988 Plan was terminated upon our initial public offering and no new options can be granted under this plan. The termination of the 1988 Plan had no effect upon outstanding options under the plan.

### Stock Option Plan Activity Summary

A summary of activity under our stock option plans through December 31, 2004 is as follows:

	Shares Available for Grant	Outstanding Options	
		Number of Shares	Weighted Avg. Price per Share
Balance, December 31, 2001 .....	1,426,302	3,521,656	\$ 5.03
Shares terminated, 1988 and 1996 plans .....	(10,839)	—	—
Authorized .....	1,388,274	—	—
Granted .....	(1,933,500)	1,933,500	\$11.48
Exercised .....	—	(246,861)	\$ 4.73
Cancelled .....	357,630	(357,630)	\$10.18
Balance, December 31, 2002 .....	1,227,867	4,850,665	\$ 7.24
Shares terminated, 1988 and 1996 plans .....	(35,087)	—	—
Authorized .....	1,500,000	—	—
Granted .....	(1,201,500)	1,201,500	\$15.06
Exercised .....	—	(304,829)	\$ 5.28
Cancelled .....	450,326	(450,326)	\$ 8.88
Balance, December 31, 2003 .....	1,941,606	5,297,010	\$ 8.99
Authorized .....	1,500,000	—	—
Granted .....	(2,550,500)	2,550,500	\$21.45
Exercised .....	—	(157,461)	\$ 5.50
Cancelled .....	216,705	(216,705)	\$18.32
Balance, December 31, 2004 .....	<u>1,107,811</u>	<u>7,473,344</u>	\$13.04

The weighted-average fair value of options granted during 2004, 2003 and 2002 was \$12.96, \$9.55 and \$6.34. The weighted-average exercise price of options exercisable during 2004, 2003 and 2002 was \$6.94, \$4.88 and \$3.49.

The following table summarizes information about the stock options outstanding at December 31, 2004:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Number of Shares	Weighted Average Remaining Contractual Life (in Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
\$ 1.00 – \$ 2.00 .....	1,199,665	3.63	\$ 1.62	1,199,665	\$ 1.62
\$ 3.81 – \$ 7.20 .....	444,700	6.22	\$ 4.90	420,304	\$ 4.86
\$ 7.21 – \$10.99 .....	1,315,883	6.94	\$ 9.71	859,295	\$ 9.45
\$11.00 – \$18.53 .....	1,781,096	7.75	\$12.51	785,243	\$12.34
\$18.60 – \$23.76 .....	1,656,250	9.69	\$19.49	61,252	\$20.70
\$24.13 – \$29.04 .....	1,075,750	9.06	\$24.19	0	\$ 0.00
\$ 1.00 – \$29.04 .....	<u>7,473,344</u>	7.48	\$13.04	<u>3,325,759</u>	\$ 6.94

### Deferred Compensation

During the years ended December 31, 2000 and 1999, in connection with options granted to employees, we recorded deferred stock compensation of \$2.6 million and \$260,000, representing the difference between the exercise price of the options and the deemed fair value of the common stock. These amounts are being amortized to operations over the vesting periods of the options on a straight-line basis.

We recorded amortization of deferred stock compensation of approximately \$93,000, \$419,000 and \$511,000 for the years ended December 31, 2004, 2003 and 2002.

### Reserved Shares

At December 31, 2004, common stock subject to future issuance is as follows:

1996 Stock option plan .....	1,199,665
2000 Equity incentive plan .....	7,130,031
2000 Non-employee directors' stock option plan .....	251,459
2000 Employee stock purchase plan .....	540,065
	<u>9,121,220</u>

## 7. Income Taxes

We have incurred net losses since inception and, consequently, have not recorded any U.S. federal and state income taxes. Deferred income taxes reflect the net tax effects of net operating loss and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets are as follows:

	December 31,	
	2004	2003
	(in thousands)	
Deferred tax assets		
Net operating loss carryforward .....	\$ 81,070	\$ 56,626
Tax credits .....	16,498	11,941
Capitalized research expenses .....	6,648	4,777
Other .....	794	708
Total deferred tax assets .....	105,010	74,052
Valuation allowance .....	(105,010)	(74,052)
Net deferred tax assets .....	<u>\$ —</u>	<u>\$ —</u>

The provision for income taxes differs from the expected tax expense amount computed by applying the statutory federal income tax rate to income (loss) before taxes as follows:

	December 31,	
	2004	2003
	(in thousands)	
Federal statutory tax expense .....	\$(23,737)	\$(17,218)
State tax, net of federal income tax benefit .....	(4,073)	(2,955)
Research and development credit .....	(3,453)	(7,390)
Valuation allowance .....	30,958	27,502
Other individually immaterial items .....	305	61
Provision for taxes .....	<u>\$ —</u>	<u>\$ —</u>

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$31.0 million and \$27.5 million during 2004 and 2003.

As of December 31, 2004, we had net operating loss carryforwards of approximately \$224.2 million for federal and \$83.1 million for state income tax purposes. If not utilized, these carryforwards will begin to expire beginning in 2005 for federal purposes and 2005 for state purposes. Approximately \$5.5 million of the federal and state net operating loss carryforwards represents the stock option deduction arising from activity under the Company's stock option plan, the benefit of which will increase additional paid in capital when realized.

We have research credit carryforwards of approximately \$11.1 million and \$7.9 million for federal and state income tax purposes. If not utilized, the federal carryforwards will expire in various amounts beginning in 2005. The state credit can be carried forward indefinitely.

The Internal Revenue Code limits the use of net operating loss and tax credit carryforwards in certain situations where changes occur in the stock ownership of a company. In the event we have a change in ownership, utilization of the carryforwards could be restricted.

## 8. Related Party Transaction

From October 1998 to October 2001, Gail L. Brown, M.D. served as a consultant to Telik on matters involving the clinical development of our products. Dr. Brown is the spouse of Dr. Michael Wick, our President, Chief Executive Officer and Chairman. In November 2001, Dr. Brown joined Telik as Senior Vice President and Chief Medical Officer.

## 9. 401(k) Plan

We maintain a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code. The plan covers substantially all employees over the age of 21. Participating employees may defer a portion of their pretax earnings, up to the Internal Revenue Service annual contribution limit. We have made no employer contributions to the plan since its inception.

## 10. Subsequent Events

In April 2004, we filed a registration statement on Form S-3 to offer and sell, from time to time, equity securities in one or more offerings up to a total dollar amount of \$200 million. On February 2, 2005, we sold 7,000,000 shares of common stock at a price of \$18.75 per share in an underwritten public offering pursuant to this registration statement. On February 9, 2005, the underwriters fully exercised their option to purchase 1,050,000 shares of our common stock at \$18.75 per share from us to cover over-allotments. We received approximately \$142.6 million in net proceeds after deducting underwriting discounts and commissions. As of February 9, 2005, total shares of common stock outstanding after this offering is 51,882,529.

In January 2005, we renegotiated payment terms for the \$2.0 million in leasehold improvements financed by our lessor. The \$2.0 million balloon payment was originally due at the commencement of 2005. The lessor agreed to amortize the payment of the \$2.0 million at an interest rate of 6% over twelve months with equal monthly payments of principal and interest of approximately \$172,000 through December 31, 2005.

# 11. Quarterly Financial Information (unaudited)

Selected quarterly financial information is summarized below (in thousands except per share amounts):

Quarter ended	2004				2003			
	Dec. 31	Sep. 30	Jun. 30	Mar. 31	Dec. 31	Sep. 30	Jun. 30	Mar. 31
Total revenues .....	\$ 44	\$ 44	\$ 44	\$ 31	\$ 7	\$ 6	\$ 173	\$ 250
Operating costs and expenses:								
Research and development .....	18,805	14,250	15,576	13,237	11,660	10,671	10,262	9,718
General and administrative .....	2,709	2,551	2,734	2,619	3,202	2,628	2,080	2,005
Total operating costs and expenses .....	21,514	16,801	18,310	15,856	14,862	13,299	12,342	11,723
Loss from operations .....	(21,470)	(16,757)	(18,266)	(15,825)	(14,855)	(13,293)	(12,169)	(11,473)
Interest income, net .....	708	695	540	558	325	190	271	362
Net loss .....	<u>\$(20,762)</u>	<u>\$(16,062)</u>	<u>\$(17,726)</u>	<u>\$(15,267)</u>	<u>\$(14,530)</u>	<u>\$(13,103)</u>	<u>\$(11,898)</u>	<u>\$(11,111)</u>
Net loss per common share, basic and diluted (1) .....	\$ (0.47)	\$ (0.37)	\$ (0.41)	\$ (0.35)	\$ (0.36)	\$ (0.37)	\$ (0.33)	\$ (0.31)
Weighted average shares used in computing net loss per common share, basic and diluted .....	43,777	43,714	43,691	43,621	39,822	35,895	35,840	35,657

(1) Net loss per common share for each quarter are calculated as a discrete period; the sum of four quarters may not equal the calculated full year amount

### CERTIFICATIONS

I, Michael M. Wick, M.D., Ph.D., certify that:

1. I have reviewed this annual report on Form 10-K of Telik, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2005

/s/ MICHAEL M. WICK

Michael M. Wick, M.D., Ph.D.  
Chairman and Chief Executive Officer



**CERTIFICATIONS**

I, Cynthia M. Butitta, certify that:

1. I have reviewed this annual report on Form 10-K of Telik, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2005

/s/ CYNTHIA M. BUTITTA

Cynthia M. Butitta  
Chief Operating Officer and Chief Financial Officer

**CERTIFICATION**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Michael M. Wick, M.D., Ph.D., Chairman and Chief Executive Officer of Telik, Inc. (the "Company"), and Cynthia M. Butitta, Chief Operating Officer and Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2004, to which this Certification is attached as Exhibit 32.1 (the "Annual Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, as amended; and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 9th day of March, 2005.

/s/ MICHAEL M. WICK

Michael M. Wick, M.D., Ph.D.  
Chairman and Chief Executive Officer

/s/ CYNTHIA M. BUTITTA

Cynthia M. Butitta  
Chief Operating Officer and Chief Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Telik, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

# Corporate Directory and Information

## Board of Directors

**Michael M. Wick, M.D., Ph.D.**  
*Chairman, Chief Executive Officer  
and President, Telik, Inc.*

**Edward W. Cantrall, Ph.D.**  
*Biotechnology and Genomics Consultant*

**Robert W. Frick**  
*Financial and Business Strategy Consultant  
Former Vice Chairman and  
Chief Financial Officer, Bank of America*

**Steven R. Goldring, M.D.**  
*Professor of Medicine, Harvard Medical School  
Chief of Rheumatology, Beth Israel Deaconess  
Medical Center*

**Mary Ann Gray, Ph.D.**  
*President, Gray Strategic Advisors, LLC*

**Richard B. Newman, Esq.**  
*President and Chief Executive Officer  
D&R Products Co., Inc.*

**Stefan Ryser, Ph.D.**  
*Managing Partner  
Bear Stearns Health Innoventures L.P.*

**Herwig von Morzé, Ph.D.**  
*International Patent Consultant*

## Executive Officers

**Michael M. Wick, M.D., Ph.D.**  
*Chairman, Chief Executive Officer  
and President*

**Cynthia M. Butitta**  
*Chief Operating Officer and  
Chief Financial Officer*

**Reinaldo F. Gomez, Ph.D.**  
*Senior Vice President, Product Development*

**Marc L. Steuer**  
*Senior Vice President, Business Development*

## Key Personnel

**Gail L. Brown, M.D.**  
*Senior Vice President and  
Chief Medical Officer*

**William P. Kaplan, Esq.**  
*Vice President, Legal Affairs*

**James E. Keck, Ph.D.**  
*Vice President, Biology Research*

**David W. Lair**  
*Vice President, Finance and Clinical Operations*

**Robert T. Lum, Ph.D.**  
*Vice President, Preclinical Development*

**Carlos A. Parra**  
*Vice President, Quality*

**Steven R. Schow, Ph.D.**  
*Vice President, Chemistry Research*

**Bhavender Sharma, Ph.D.**  
*Vice President, Manufacturing*

**Jay P. Shepard**  
*Vice President, Commercial Operations*

## Corporate Headquarters

**Telik, Inc.**  
3165 Porter Drive  
Palo Alto, CA 94304  
Tel: 650 845 7700  
Fax: 650 845 7800  
Web: [www.telik.com](http://www.telik.com)  
Email: [inquiry@telik.com](mailto:inquiry@telik.com)

## Transfer Agent and Registrar

**EquiServe Trust Company, N.A.**  
250 Royall Street  
Canton, MA 02021  
Tel: 781 575 3400  
Web: [www.equiserve.com](http://www.equiserve.com)

## Legal Counsel

**Cooley Godward LLP**  
Palo Alto, CA

## Independent Auditors

**Ernst & Young LLP**  
Palo Alto, CA

## Annual Meeting

Telik's annual stockholders meeting will be held on May 26, 2005 at 11:00 a.m. at company headquarters.

## Report on Form 10-K

Additional information constituting part of this 2004 annual report is contained in Telik's Annual Report on Form 10-K for the year ended December 31, 2004, a copy of which is included herewith. Additional copies of the Form 10-K may be obtained by contacting us by mail, telephone, fax or Email.

## Stock Market Information

Telik's common stock is traded on the Nasdaq National Market under the symbol TELK.

This annual report contains forward-looking statements. For this purpose, any statements contained in this annual report that are not statements of historical fact may be deemed to be forward-looking statements, including any statements regarding the potential for TELCYTA™ or TELINTRA™ to treat one or more types of cancer. Detailed information regarding factors that may cause actual results to differ materially from the results expressed or implied by statements in this press release may be found in Telik's periodic filings with the Securities and Exchange Commission, including the factors described in the section entitled "Risk Factors" in its Annual Report on Form 10-K for the year ended December 31, 2004, a copy of which is provided with this annual report. Telik assumes no obligation to update or revise any forward-looking statements in this annual report.

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Telix, Inc.

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